

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and	)	
SANOFI-AVENTIS U.S. LLC,	)	
	)	
Plaintiffs,	)	
v.	)	C.A. No. 07-792 (GMS)
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	

**DECLARATION OF WILLIAM T. VUK  
IN SUPPORT OF PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO  
DEFENDANTS' MOTION TO TRANSFER IN FAVOR OF PENDING FLORIDA  
JURISDICTION, OR IN THE ALTERNATIVE TO STAY THE DELAWARE ACTION**

I, William T. Vuk, declare:

I am an attorney with the law firm Kirkland & Ellis LLP, counsel for sanofi-aventis and sanofi-aventis U.S. LLC. I submit this declaration in support of Plaintiffs' Answering Brief in Opposition to Defendants' Motion to Transfer In Favor of Pending Florida Jurisdiction, or In the Alternative To Stay the Delaware Action and have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit A is a true and accurate copy of Apotex Inc. - Corporate Info, <http://www.apotex.com/CorporateInformation/Default.asp?flash=Yes> (last visited January 31, 2008).
2. Attached hereto as Exhibit B is a true and accurate copy of a letter dated August 14, 2007 from Bernard C. Sherman to Sanofi-Aventis US and Sanofi-Aventis and Jagotec AG.
3. Attached hereto as Exhibit C is a true and accurate copy of a letter dated October 25, 2007 from Bernard C. Sherman to Sanofi-Aventis US and Sanofi-Aventis and Jagotec AG.



4. Attached hereto as Exhibit D is a true and accurate copy of the Complaint dated September 21, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Actavis South Atlantic LLC, et al.*, Civil Action No. 07-572 (GMS) (MPT), in the District Court for the District of Delaware.

5. Attached hereto as Exhibit E is a true and accurate copy of the Complaint dated September 21, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Barr Laboratories, Inc.*, Civil Action No. 07-574 (GMS) (MPT), in the District Court for the District of Delaware.

6. Attached hereto as Exhibit F is a true and accurate copy of a letter dated October 1, 2007 from William T. Vuk to Bernice Tao.

7. Attached hereto as Exhibit G are true and correct copies of:

- excerpts from Defendants Apotex Inc.'s and Apotex Corp.'s Answer, Defenses, and Counterclaims dated June 11, 2007 filed in *Allergan, Inc. v. Apotex, Inc. and Apotex Corp.*, Civil Action No. 07-278-GMS, in the District Court for the District of Delaware;
- excerpts from Defendants Apotex Inc.'s and Apotex Corp.'s Answer, Defenses, and Counterclaims dated May 30, 2007 filed in *Medpointe Healthcare Inc. v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-204-SLR, in the District Court for the District of Delaware;
- excerpts from Answer of Apotex Inc. and Apotex Corp. to Plaintiff's Amended Complaint, Affirmative Defenses and Counterclaims dated April 14, 2006 filed in *Medpointe Healthcare Inc. v. Apotex Inc. and Apotex Corp.*, Civil Action No. 06-164 (SLR), in the District Court for the District of Delaware;
- excerpts from Defendant Apotex, Inc.'s Answer, Affirmative Defenses and Counterclaims dated May 9, 2006 filed in *Merck & Co., Inc. v. Apotex, Inc.*, Civil Action No. 06-230-GMS, in the District Court for the District of Delaware; and
- Complaint for Declaratory Judgment and Demand for Jury Trial dated October 29, 2003 filed in *Torpharm Inc., Apotex Corp., and Apotex, Inc., v. Pfizer Inc. and Warner-Lambert Company*, Civil Action No. 03-990, in the District Court for the District of Delaware.

8. Attached hereto as Exhibit H is a true and accurate copy of a letter dated December 6, 2007 from William T. Vuk to Dr. Bernard Sherman and Tammy McIntyre.



9. Attached hereto as Exhibit I is a true and accurate copy of an email dated December 11, 2007 from Maryellen Noreika to Sherry L. Rollo.

10. Attached hereto as Exhibit J is a true and accurate copy of a letter dated December 31, 2007 from Maryellen Noreika to Sherry L. Rollo.

11. Attached hereto as Exhibit K is a true and accurate copy of a letter dated January 7, 2008 from Steven E. Feldman to William T. Vuk.

12. Attached hereto as Exhibit L is a true and accurate copy of a letter dated January 7, 2008 from William T. Vuk to Steven E. Feldman.

13. Attached hereto as Exhibit M is a true and accurate copy of the Complaint dated December 10, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

14. Attached hereto as Exhibit N is a true and accurate copy of Plaintiffs' Motion to Transfer or Stay and Supporting Memorandum of Law dated January 8, 2008 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida

15. Attached hereto as Exhibit O is a true and accurate copy of the Answer of Apotex Inc. and Apotex Corp. to Complaint, Affirmative Defenses and Counterclaims dated December 28, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

16. Attached hereto as Exhibit P is a true and accurate copy of the Answer of Apotex Inc. and Apotex Corp. to Complaint, Affirmative Defenses and Amended Counterclaims dated



January 2, 2008 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

17. Attached hereto as Exhibit Q is a true and accurate copy of Defendants Apotex Inc.'s and Apotex Corp.'s Rule 26(a)(1) Initial Disclosures dated January 17, 2008 served in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

18. Attached hereto as Exhibit R is a true and accurate copy of a letter dated January 17, 2008 from William T. Vuk to Steven E. Feldman and Stephen J. Bronis.

19. Attached hereto as Exhibit S is a true and accurate copy of Plaintiffs' Initial Disclosures Pursuant to Rule 26(a)(1) dated January 31, 2008 served in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

20. Attached hereto as Exhibit T is a compendium of the unreported cases cited in Plaintiffs' Answering Brief In Opposition to Defendants' Motion To Transfer In Favor Of Pending Florida Jurisdiction, Or In The Alternative To Stay The Delaware Action.

I declare under penalty of perjury that the foregoing is true and accurate.

/s/ William T. Vuk

William T. Vuk

January 31, 2008  
New York, New York  
1446347



**CERTIFICATE OF SERVICE**

I hereby certify that on January 31, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

Richard L. Horwitz, Esquire  
Kenneth L. Dorsney, Esquire  
POTTER ANDERSON & CORROON LLP

I further certify that I caused to be served copies of the foregoing document on January 31, 2008 upon the following in the manner indicated:

Richard L. Horwitz, Esquire  
Kenneth L. Dorsney, Esquire  
POTTER ANDERSON & CORROON LLP  
Hercules Plaza – 6<sup>th</sup> Floor  
1313 North Market Street  
Wilmington, DE 19801

*VIA ELECTRONIC MAIL  
and HAND DELIVERY*

Robert B. Breisblatt, Esquire  
Steven E. Feldman, Esquire  
Sherry L. Rollo, Esquire  
WELSH & KATZ LTD.  
120 S. Riverside Plaza  
22<sup>nd</sup> Floor  
Chicago, IL 60606

*VIA ELECTRONIC MAIL*

*/s/ Maryellen Noreika*

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Maryellen Noreika (#3208)



# **EXHIBIT A**



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## CORPORATE INFO

Apotex Inc. was founded in 1974, and is the largest Canadian-owned pharmaceutical company. From its 2 employees, 5,000 square foot beginning, the company has grown to employ over 6,500 people in research, development, manufacturing and distribution facilities world-wide. The Canadian operations of the Apotex Group of Companies with approximately 5,500 employees now occupy over 3.4 million square feet in Montreal, Richmond Hill, Toronto, Etobicoke, Mississauga, Brantford, Windsor, Winnipeg, Calgary and Vancouver.

In the last few years, Apotex has hired over 1200 new employees in Production, Engineering, Operations, Quality and Research. Out of the total employee base, there are over 2,100 scientific staff including over 110 PhD's. To meet the growing world demand for Apotex medicines, hundreds of new qualified technical professionals need to be hired. Apotex produces more than 300 generic pharmaceuticals in over 4000 dosages and formats which, in Canada, are used to fill over 70 million prescriptions a year - the largest amount of any pharmaceutical company in this country.

[→Chairman's Message](#)[→President's Message](#)

Today, Apotex is a necessary and trusted member of Canada's healthcare community. The company's pharmaceuticals can be found in virtually every pharmacy and healthcare facility in Canada and are exported to over 115 countries around the globe. Export markets represent an ever growing portion of the total sales. Apotex has also established a presence through subsidiaries, joint ventures or licensing agreements in the Czech Republic, Mexico, China, Poland, New Zealand, France, and Italy, to name just a few. Healthcare professionals around the world rely on Apotex for quality and value.

Although the company's own business is developing and manufacturing generic pharmaceuticals, the success of Apotex has enabled it to diversify into a number of other health-related areas. The Apotex Pharmaceutical Group of Companies also researches, develops, manufactures and distributes fine chemicals, non-prescription and private label medicines, and disposable plastics for medical use.

The worldwide sales of the Apotex Group of companies exceed \$1 billion (Canadian \$) per year.

[→Leading the Way With Research and Development](#)

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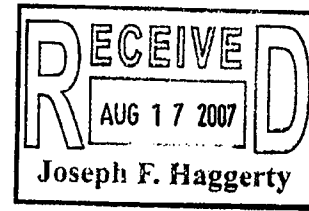


# **EXHIBIT B**





August 14, 2007



Sanofi-Aventis US  
55 corporate Drive  
Bridgewater, NJ 08807

and

Sanofi-Aventis and Jagotec AG  
c/o Jacobson Holman PLLC  
400 Seventh St. NW  
Washington, DC 20004

Attention: Harvey B. Jacobson Jr.

Re: Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of  
the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95

Dear Sir or Madam:

Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, we advise you, as the New Drug Application ("NDA") holder for the reference drug and the patent owner of the listed patent, that the United States Food and Drug Administration ("FDA") has received an Abbreviated New Drug Application ("ANDA") from Apotex Inc. (hereinafter "Apotex") for alfuzosin hydrochloride extended release tablets of 10 mg strength. Apotex's ANDA was submitted under 21 U.S.C. § 355(j)(1) and 2(A) with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of U.S. Patent No. 6149940 ("the '940 patent").

Required Disclosures under 21 C.F.R. § 314.95(c)

Pursuant to 21 C.F.R. § 314.95(c)(1), we advise you that FDA has received an ANDA from Apotex containing any required bioavailability or bioequivalence data or information from studies on alfuzosin hydrochloride extended release tablets.

Pursuant to 21 C.F.R. § 314.95(c)(2), we advise you that the ANDA submitted by Apotex has been assigned ANDA No. 79-013 by the FDA.

Pursuant to 21 C.F.R. § 314.95(c)(3), we advise you that the established name of the drug product that is the subject of Apotex's ANDA is "Alfuzosin Hydrochloride Extended Release Tablets".



Pursuant to 21 C.F.R. § 314.95(c)(4), we advise you that the active pharmaceutical ingredient of Apotex's proposed drug product is alfuzosin hydrochloride. The proposed method of administration is oral.

Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the patent in the paragraph IV certification, alleged to be not infringed is the '940 patent.

Detailed Statement

Apotex alleges, and has certified to the FDA, that in its opinion and to the best of its knowledge, each claim of the '940 patent will not be infringed by the commercial manufacture, use or sale of the drug product described by Apotex's ANDA No. 79-013. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(6), Apotex's detailed statement of the legal and factual basis for the certification set forth in Apotex's ANDA is as follows:

The claims of the '940 patent are limited to a tablet comprising at least two layers, one of which contains alfuzosin hydrochloride. Our tablets will not infringe because they do not comprise two or more layers but are comprised of a single homogenous matrix.

Apotex certifies pursuant to 21 C.F.R. § 314.95(c)(7) that:

Tammy McIntire  
Apotex Corp.  
2400 N. Commerce Parkway  
Suite 400  
Weston, FL 33326

Is hereby authorized to accept service of process on behalf of Apotex in connection with its ANDA No. 79-013 relating to alfuzosin hydrochloride extended release tablets.

Offer of Confidential Access to Application Pursuant to 21 U.S.C. § 355(j)(5)(c)

Apotex offers to provide confidential access to certain information from its ANDA for the sole and exclusive purpose of determining whether an infringement action referred to in 21 U.S.C. § 355(j)(5)(c)(i)(III) can be brought.

21 U.S.C. § 355(j)(5)(C)(i)(III) allows Apotex to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." That provision also



grants Apotex the right to redact its ANDA in response to a request for Confidential Access under this offer.

As permitted by statute, Apotex imposes the following terms and restrictions on its Offer of Confidential access:

1. Apotex will permit confidential access to certain information from its proprietary ANDA to attorneys from one outside law firm representing you; provided, however, that such attorneys do not engage, formally or informally, in any patent prosecution for you or any FDA counseling, litigation or other work before or involving FDA. Such information (hereinafter, "Confidential Apotex Information") shall be marked "CONFIDENTIAL".
2. The attorneys from the outside law firm representing you shall not disclose any Confidential Apotex Information to any other person or entity, including your employees, outside scientific consultants, and/or other outside counsel retained by you, without one prior written consent.
3. As provided by § 355(j)(5)(c)(i)(III), your outside law firm shall make use of the Confidential Apotex Information for the sole and exclusive purpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought and for no other purpose. Your outside law firm agrees to take all measures necessary to prevent unauthorized disclosure or use of the Confidential Information, and that all Confidential Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access.
4. The Confidential Information disclosed is, and remains, the property of Apotex.
5. By providing the Confidential Information, Apotex does not grant your outside law firm any interest in or license for the Confidential Information. Your outside law firm shall, within thirty-five (35) days from the date that it first receives the Confidential Information, return to Apotex, all Confidential Information and any copies thereof. Your outside law firm shall return all Confidential Information to Apotex before any infringement suit is filed by you. In the event that you opt to file suit, none of the information contained in or obtained from any Confidential Information that Apotex provides shall be included in any publicly-available complaint or other pleading.
6. Nothing in this Offer of Confidential Access shall be construed as an admission by Apotex regarding the validity, enforceability, and/or



infringement of any U.S. patent. Further, nothing herein shall be construed as an agreement or admission by Apotex with respect to the competency, relevance, or materiality of any such Confidential Information, document, or thing. The fact that Apotex provides Confidential Information upon your request shall not be construed as an admission by Apotex that such Confidential Information is relevant to the disposition of any issue relating to any alleged infringement of any patent, or to the validity or enforceability of any patent.

7. The attorneys from your outside law firm shall acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any Confidential Information.

Section 355(j)(5)(C)(i)(III) further provides that any request for access that you make under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access", and that the "restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract". Thus, to the extent that you request access to Confidential Apotex Information, you mandatorily accept the terms and restrictions attached hereto. Written notice requesting access under this Offer of Confidential Access should be made to:

Bernice Tao  
Apotex Inc.  
150 Signet Drive  
Toronto, Ontario M9L 1T9

#### Reservation of Legal Rights

Apotex reserves the right to allege the same, similar, different or new theories of non-infringement, invalidity, and/or unenforceability, and nothing in the Notice Letter or Detailed Statement shall be construed as to limit Apotex's rights to make any allegation in any subsequent litigation regarding any issue.

Yours very truly,

APOTEX INC.



Bernard C. Sherman, Ph.D., P.Eng.  
Chairman and C.E.O.



# **EXHIBIT C**



# CONFIDENTIAL EXHIBIT



# **EXHIBIT D**



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and  
SANOFI-AVENTIS U.S. LLC,  
Plaintiffs,

vs.

ACTAVIS SOUTH ATLANTIC LLC,  
AUROBINDO PHARMA LTD.,  
AUROBINDO PHARMA USA INC.,  
MYLAN PHARMACEUTICALS INC., PAR  
PHARMACEUTICAL, INC., RANBAXY  
INC., RANBAXY LABORATORIES  
LIMITED, SUN PHARMACEUTICAL  
INDUSTRIES, INC., SUN  
PHARMACEUTICAL INDUSTRIES LTD,  
TEVA PHARMACEUTICALS USA, INC.,  
TORRENT PHARMA INC. and TORRENT  
PHARMACEUTICALS LIMITED,

Defendants.

C.A. No. - 07 - 57  
FILED  
U.S. DISTRICT COURT  
DISTRICT OF DELAWARE  
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COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd. ("Aurobindo Ltd."), Aurobindo Pharma USA Inc. ("Aurobindo Inc."), Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc. ("Par"), Ranbaxy Inc., Ranbaxy Laboratories Limited ("Ranbaxy Ltd."), Sun Pharmaceutical Industries, Inc. ("Sun Inc."), Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Teva Pharmaceuticals USA, Inc. ("Teva"), Torrent Pharma Inc. ("Torrent Inc.") and Torrent Pharmaceuticals Ltd. ("Torrent Ltd."), hereby allege as follows:



Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.
2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
3. Upon information and belief, Defendant Actavis is a Delaware limited liability company having a place of business at 13800 NW 2nd Street, Ste-190, Fort Lauderdale, Florida 33325.
4. Upon information and belief, Defendant Aurobindo Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Aurobindo Ltd., having a place of business at 2400 Route 130 North, Dayton, New Jersey 08810.
5. Upon information and belief, Defendant Aurobindo Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Upon information and belief, Defendant Aurobindo Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Aurobindo Inc.
6. Upon information and belief, Defendant Mylan is a West Virginia corporation having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26504. Upon information and belief, Defendant Mylan manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.
7. Upon information and belief, Defendant Par is a Delaware corporation having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.



8. Upon information and belief, Defendant Ranbaxy Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Ranbaxy Ltd., having a place of business at 600 College Road East, Princeton, New Jersey 08540.

9. Upon information and belief, Defendant Ranbaxy Ltd. is an Indian corporation having a place of business at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India. Upon information and belief, Defendant Ranbaxy Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Ranbaxy Inc.

10. Upon information and belief, Defendant Sun Inc. was a Michigan corporation, and the wholly-owned subsidiary and agent of Defendant Sun Ltd., having a place of business at 29714 Orion CT, Farmington Hills, Michigan 48334 at the time it submitted its Abbreviated New Drug Application. Upon information and belief, Sun Inc. dissolved as a corporation on or about July 15, 2007. Upon information and belief, Defendant Sun Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

11. Upon information and belief, Defendant Sun Ltd. is an Indian corporation having a place of business at Acme Plaza, Andheri - Kurla Rd, Andheri (E), Mumbai - 400 059. Upon information and belief, Defendant Sun Ltd., itself and through its wholly-owned subsidiary and agent Defendant Sun Inc., manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

12. Upon information and belief, Defendant Teva is a Delaware corporation having a place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.



13. Upon information and belief, Defendant Torrent Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Torrent Ltd., having a place of business at 3585 Bellflower Drive, Portage, Michigan 49024.

14. Upon information and belief, Defendant Torrent Ltd. is an Indian company having a place of business at Torrent House, Off Ashram Road, Ahmedabad - 380 009, Gujarat, India. Upon information and belief, Defendant Torrent Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Torrent Inc.

#### Nature of the Action

15. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A) and United States Patent No. 6,149,940 ("the '940 patent") (Exhibit B). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

#### Jurisdiction and Venue

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

17. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware company, Plaintiff sanofi-aventis U.S. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

18. This Court has personal jurisdiction over Defendant Actavis by virtue of the fact that, *inter alia*, Actavis is a Delaware limited liability company.



19. This Court has personal jurisdiction over Defendant Aurobindo Inc. by virtue of the fact that, *inter alia*, Aurobindo Inc. is a Delaware corporation.

20. This Court has personal jurisdiction over Defendant Aurobindo Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Aurobindo Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Aurobindo Inc.

21. This Court has personal jurisdiction over Defendant Mylan by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

22. This Court has personal jurisdiction over Defendant Par by virtue of the fact that, *inter alia*, Par is a Delaware corporation.

23. This Court has personal jurisdiction over Defendant Ranbaxy Inc. by virtue of the fact that, *inter alia*, Ranbaxy Inc. is a Delaware corporation.

24. This Court has personal jurisdiction over Defendant Ranbaxy Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Ranbaxy Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Ranbaxy Inc.

25. This Court has personal jurisdiction over Defendant Sun Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

26. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its subsidiary and agent Sun Inc.

27. This Court has personal jurisdiction over Defendant Teva by virtue of the fact that, *inter alia*, Teva is a Delaware corporation.



28. This Court has personal jurisdiction over Defendant Torrent Inc. by virtue of the fact that, *inter alia*, Torrent Inc. is a Delaware corporation.

29. This Court has personal jurisdiction over Defendant Torrent Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Torrent Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Torrent Inc.

30. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

#### The Patents

31. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

32. On November 21, 2000, the '940 patent, titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate," was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the Orange Book for Uroxatral®.



**Acts Giving Rise to this Action**

**Count I – Infringement of the ‘491 Patent by Defendants Actavis and Par**

33. Upon information and belief, Actavis submitted Abbreviated New Drug Application (“ANDA”) 79-055 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-055 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis’ Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the ‘491 patent.

34. Actavis alleged in ANDA 79-055 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the ‘491 patent are invalid. Plaintiffs received written notification of ANDA 79-055 on or about August 17, 2007.

35. Actavis’ submission of ANDA 79-055 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the ‘491 patent under 35 U.S.C. § 271(e)(2)(A). Actavis’ commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis’ Uroxatral® brand product would infringe the ‘491 patent.

36. Par is jointly and severally liable for Actavis’ infringement of the ‘491 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or induced Actavis’ submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

37. Par’s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the ‘491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Par’s



commercial manufacture, use, offer for sale or sale of the proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

38. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '491 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

39. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count II – Infringement of the '940 Patent by Defendants Actavis and Par**

40. ANDA 79-055 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

41. Actavis has alleged in ANDA 79-055 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-055 on or about August 17, 2007.

42. Actavis' submission of ANDA 79-055 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Actavis' commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

43. Par is jointly and severally liable for Actavis' infringement of the '940 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or



induced Actavis' submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

44. Par's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Par's commercial manufacture, use, offer for sale or sale of its proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

45. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '940 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

46. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count III – Infringement of the '491 Patent by Defendants  
Aurobindo Ltd. and Aurobindo Inc.**

47. Upon information and belief, Aurobindo Ltd., through its subsidiary and agent Aurobindo Inc., submitted ANDA 79-060 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-060 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.



48. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

49. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

50. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infringement of the '491 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

51. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

52. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.



53. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count IV – Infringement of the ‘940 Patent by Defendants  
Aurobindo Ltd. and Aurobindo Inc.**

54. ANDA 79-060 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

55. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

56. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

57. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infringement of the '940 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

58. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the



FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

59. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

60. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count V – Infringement of the '491 Patent by Defendant Mylan**

61. Upon information and belief, Mylan submitted ANDA 79-014 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-014 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

62. Mylan alleged in ANDA 79-014 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of ANDA 79-014 on or about August 27, 2007.

63. Mylan's submission of ANDA 79-014 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C.



§ 271(e)(2)(A). Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

64. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '491 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

65. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count VI – Infringement of the '940 Patent by Defendant Mylan**

66. ANDA 79-014 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

67. Mylan alleged in ANDA 79-014 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-014 on or about August 27, 2007.

68. Mylan's submission of ANDA 79-014 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Mylan has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-014. However, given Mylan's claim of bioequivalence contained within ANDA 79-014, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation



or discovery that will demonstrate that Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

69. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '940 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

70. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count VII – Infringement of the '940 Patent by Defendants  
Ranbaxy Ltd. and Ranbaxy Inc.**

71. Upon information and belief, Ranbaxy Ltd., through its subsidiary and agent Ranbaxy Inc., submitted ANDA 79-006 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-006 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

72. Ranbaxy Ltd. alleged in ANDA 79-006 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-006 on or about August 14, 2007.

73. Ranbaxy Ltd.'s submission of ANDA 79-006 to the FDA, through Ranbaxy Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the



'940 patent under 35 U.S.C. § 271(e)(2)(A). Ranbaxy Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

74. Ranbaxy Inc. is jointly and severally liable for any infringement of the '940 patent. Upon information and belief, Ranbaxy Inc. participated in, contributed to, aided, abetted and/or induced Ranbaxy Ltd.'s submission of ANDA 79-006 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

75. Ranbaxy Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-006 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Ranbaxy Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

76. This is an exceptional case under 35 U.S.C. § 285 because Ranbaxy Ltd. and Ranbaxy Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-006 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

77. Plaintiffs will be irreparably harmed by Defendant Ranbaxy Ltd.'s and Defendant Ranbaxy Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count VIII – Infringement of the '940 Patent by Defendants Sun Inc. and Sun Ltd.**

78. Upon information and belief, Sun Inc. acting as a subsidiary and agent of Sun Ltd., submitted ANDA 79-057 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 79-057 seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of



alfuzosin hydrochloride per tablet. ANDA 79-057 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

79. Sun Inc. alleged in ANDA 79-057 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-057 on or about September 6, 2007.

80. Sun Inc.'s submission of ANDA 79-057 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Sun Inc. has provided no information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-057. However, given Sun Inc.'s claim of bioequivalence contained within ANDA 79-057, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that will demonstrate that Sun Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

81. Sun Ltd. is jointly and severally liable for Sun Inc.'s infringement of the '940 patent. Upon information and belief, Sun Ltd. participated in, contributed to, aided, abetted and/or induced Sun Inc.'s submission of ANDA 79-057 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

82. Sun Ltd.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-057 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Sun Ltd.'s



commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

83. This is an exceptional case under 35 U.S.C. § 285 because Sun Inc. and Sun Ltd. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-057 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

84. Plaintiffs will be irreparably harmed by Defendant Sun Inc.'s and Defendant Sun Ltd.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count IX – Infringement of the '491 Patent by Defendant Teva**

85. Upon information and belief, Teva submitted ANDA 79-056 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended-release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-056 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

86. Teva alleged in ANDA 79-056 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

87. Teva's submission of ANDA 79-056 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C.



§ 271(e)(2)(A). Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

88. This is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '491 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

89. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count X – Infringement of the '940 Patent by Defendant Teva**

90. ANDA 79-056 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

91. Teva alleged in ANDA 79-056 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

92. Teva's submission of ANDA 79-056 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Teva has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-056. However, given Teva's claim of bioequivalence contained within ANDA 79-056, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or



discovery that will demonstrate that Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

93. This is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '940 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

94. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count XI – Infringement of the '491 Patent by Defendants Torrent Ltd. and Torrent Inc.**

95. Upon information and belief, Torrent Ltd., through its subsidiary and agent Torrent Inc., submitted ANDA 79-054 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-054 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

96. Torrent Ltd. alleged in ANDA 79-054 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of ANDA 79-054 on or about August 16, 2007.

97. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Ltd.'s commercial use, offer for sale or sale of its



proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

98. Torrent Inc. is jointly and severally liable for any infringement of the '491 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced Torrent Ltd.'s submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

99. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

100. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

101. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count XII – Infringement of the '940 Patent by Defendants Torrent Ltd. and Torrent Inc.**

102. ANDA 79-054 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

103. Torrent Ltd. alleged in ANDA 79-054 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid and not



infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-054 on or about August 16, 2007.

104. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

105. Torrent Inc. is jointly and severally liable for Torrent Ltd.'s infringement of the '940 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

106. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Torrent Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

107. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

108. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.



**Prayer for Relief**

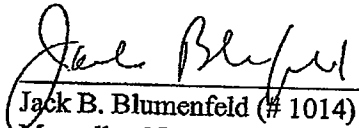
**WHEREFORE**, Plaintiffs pray for judgment as follows:

- A. That Defendants Actavis, Aurobindo Ltd., Aurobindo Inc., Mylan, Par, Teva, Torrent Inc. and Torrent Ltd. have infringed the '491 patent;
- B. That all Defendants have infringed the '940 patent;
- C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDAs identified in this Complaint shall not be earlier than the expiration dates of the '491 patent and '940 patent, including any extensions;
- D. That Defendants Actavis, Aurobindo Ltd., Aurobindo Inc., Mylan, Par, Teva, Torrent Ltd. and Torrent Inc., their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic versions of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 patent, including any extensions;
- E. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic versions of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '940 patent, prior to the expiration of the '940 patent, including any extensions;
- F. That this case is exceptional under 35 U.S.C. § 285;
- G. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and



H. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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Dated: September 21, 2007



# **EXHIBIT E**



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS )  
U.S. LLC, )

Plaintiffs, )

v. )

BARR LABORATORIES, INC., )

Defendant. )

C.A. No. - 07 - 574 -

FILED  
CLERK U.S. DISTRICT COURT  
DISTRICT OF DELAWARE  
2007 SEP 21 PM 4:06

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendant Barr Laboratories, Inc. ("Barr"), hereby allege as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174, avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Defendant Barr is a Delaware corporation having a place of business at 2 Quaker Road, Pomona, New York 10970.

Nature of the Action

4. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A) and United States Patent No. 6,149,940 ("the '940



patent”) (Exhibit B). This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

### **Jurisdiction and Venue**

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendant Barr by virtue of the fact that, *inter alia*, Barr is a Delaware corporation.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

### **The Patents**

8. On April 28, 1987, the ‘491 patent, titled “Alfuzosine Compositions and Use,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”). Plaintiff sanofi-aventis is the current assignee of the ‘491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application (“NDA”) No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The ‘491 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) for Uroxatral®.

9. On November 21, 2000, the ‘940 patent, titled “Tablet with Controlled Release of Alfuzosine Chlorhydrate,” was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the ‘940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG’s interests in the ‘940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec



AG has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the Orange Book for Uroxatral®.

**Count I – Infringement of the '491 Patent**

10. Upon information and belief, Defendant Barr submitted Abbreviated New Drug Application ("ANDA") 79-052 to the United States Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-052 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

11. Barr has alleged in ANDA 79-052 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Sanofi-aventis received written notification of Barr's ANDA 79-052 and its § 505(j)(2)(A)(vii)(IV) allegations on or about August 16, 2007.

12. Defendant Barr's submission of ANDA 79-052 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Barr's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

13. This is an exceptional case. Barr was aware of the existence of the '491 patent at the time of the submission of ANDA 79-052 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.



14. Plaintiffs will be irreparably harmed by Defendant Barr's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count II – Infringement of the '940 Patent**

15. ANDA 79-052 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

16. Barr has alleged in ANDA 79-052 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid or not infringed by the manufacture, use or sale of the proposed generic versions of sanofi-aventis' Uroxatral® brand product. Sanofi-aventis received written notification of Barr's ANDA 79-052 the § 505(j)(2)(A)(vii)(IV) allegations on or about August 16, 2007.

17. Defendant Barr's submission of ANDA 79-052 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Barr's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

18. This is an exceptional case under 35 U.S.C. § 285 because Barr was aware of the existence of the '940 patent at the time of the submission of ANDA 79-052 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

19. Plaintiffs will be irreparably harmed by Defendant Barr's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.



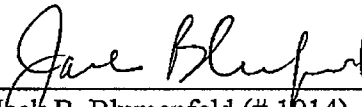
**Prayer for Relief**

**WHEREFORE**, Plaintiffs pray for judgment as follows:

- A. That Defendant Barr has infringed the '491 patent and the '940 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Barr's ANDA 79-052 shall not be earlier than the expiration dates of the '491 patent and '940 patent, including any extensions;
- C. That Defendant Barr, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling its proposed generic version of sanofi-aventis' Uroxatral® brand product, and any other product that infringes or induces or contributes to the infringement of the '491 patent or the '940 patent, prior to the expiration of those patents, including any extensions;
- D. That this case is exceptional under 35 U.S.C. § 285;
- E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur in prosecuting this action; and
- F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.



MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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*Attorneys for Plaintiffs  
sanofi-aventis and sanofi-aventis U.S. LLC*

Dated: September 21, 2007



# **EXHIBIT F**



**KIRKLAND & ELLIS LLP**

AND AFFILIATED PARTNERSHIPS

Citigroup Center  
153 East 53rd Street  
New York, New York 10022-4611

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To Call Writer Directly:  
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212 446-4900

October 1, 2007

**By Email**

Bernice Tao  
Director, Regulatory Affairs US  
Apotex Inc.  
150 Signet Drive  
Toronto, Ontario M9L 1T9

Re: Notification of Paragraph IV Certification  
for Apotex Inc.'s Alfuzosin Hydrochloride Tablets, 10 mg

Dear Ms. Tao:

By letter dated August 14, 2007, Apotex Inc. ("Apotex") indicated that it submitted Abbreviated New Drug Application ("ANDA") 79-013 for alfuzosin hydrochloride extended release tablets, 10 mg, including a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") against U.S. Patent No. 6,149,940 ("the '940 patent"). Apotex further indicated that it intends to engage in the commercial manufacture, use, import, sale and/or offer for sale of the generic 10 mg alfuzosin hydrochloride extended release product defined by ANDA 79-013 before the expiration of the '940 patent.

In compliance with the procedures provided by the Hatch-Waxman Act, we have reviewed Apotex's letter and the portions of ANDA 79-013 provided by Apotex, as well as discussed Apotex's documents and method of manufacturing with you. In connection with this review, we carefully considered, *inter alia*:

- (1) Apotex's representation at page 2 of the August 14<sup>th</sup> letter that Apotex's proposed alfuzosin hydrochloride tablets "do not comprise two or more layers;" and
- (2) Apotex's representations in the portions of ANDA 79-013 provided regarding the composition of its proposed generic alfuzosin hydrochloride extended release product and the method of manufacturing for that product.

In reliance on Apotex's representations in its letter, the portions of ANDA 79-013 provided and the conversation with you, including the specific representations recited above,



KIRKLAND & ELLIS LLP

Bernice Tao  
October 1, 2007  
Page 2

sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") will not file an action for infringement of the '940 patent against Apotex at this time. Sanofi-aventis, however, reserve the right to file such an action if they learn that Apotex's representations were incorrect or if Apotex or any other party amends ANDA 79-013.

In this regard, we remind Apotex that it is required to submit to the U.S. Food and Drug Administration an additional certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '940 patent if it amends ANDA 79-013 to change the composition or the method of manufacturing of the generic alfuzosin hydrochloride product defined therein. To the extent that Apotex makes any such certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), it must also provide sanofi-aventis with the notice required by 21 U.S.C. § 355(j)(2)(B).

Sincerely,

A handwritten signature in black ink, appearing to read 'W. T. Vuk', with a long horizontal line extending to the right.

William T. Vuk

cc: Dr. Bernard C. Sherman (via Federal Express)



# **EXHIBIT G**



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ALLERGAN, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 07-278-GMS
	)	
APOTEX, INC. and APOTEX CORP.,	)	<b>JURY TRIAL DEMANDED</b>
	)	
Defendants.	)	

**DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S ANSWER,  
DEFENSES, AND COUNTERCLAIMS.**

Defendants Apotex Inc. and Apotex Corp., for their Answer, Defenses, and Counterclaims, to the Complaint of Allergan, Inc. ("Allergan" or "Plaintiff"), state and allege as follows:

**THE NATURE OF THE ACTION**

1. This is an action for infringement of United States Patents Nos. 5,424,078, ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent") under 35 U.S.C. §271(e)(2).

**ANSWER:** Apotex Inc. and Apotex Corp. admit that the Complaint alleges infringement of United States Patents Nos. 5,424,078, ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent") under 35 U.S.C. §271(e)(2); otherwise denied.

**THE PARTIES**

2. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.



**ANSWER:** Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

3. On information and belief, defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

**ANSWER:** Admitted that Apotex Inc. is a Canadian corporation with a place of business in Ontario Canada, all other allegations are denied.

4. On information and belief, defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

**ANSWER:** Admitted.

5. On information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

**ANSWER:** Admitted.

6. On information and belief, Apotex Corp. sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

**ANSWER:** Apotex Inc. and Apotex Corp. admit that Apotex Corp. sells generic drug products manufactured by Apotex Inc. throughout the United States, including this judicial district; otherwise denied.

#### **JURISDICTION AND VENUE**

7. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, et seq. This Court has subject matter jurisdiction over the action under 28 U.S.C. §1331 and 1338.



**ANSWER:** Apotex Inc. and Apotex Corp. admit that Allergan purports to bring this action under the patent laws of the United States, Title 35, Section 1, et seq. Apotex Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the action under 28 U.S.C. §1331 and 1338(a). Except where specifically admitted, the allegations in this paragraph are otherwise denied.

8. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Defendants.

**ANSWER:** Admitted that the Court has personal jurisdiction over Apotex Inc. and Apotex Corp.; otherwise denied.

9. Venue is proper in this Court under 28 U.S.C. §1391 and 1400(b).

**ANSWER:** Admitted.

#### **BACKGROUND**

10. The '078 patent, entitled "Aqueous Ophthalmic Formulations and Methods for Preserving Same," issued to Anthony Dziabo and Paul Ripley on June 13, 1995. A copy of the '078 patent is attached to this complaint as Exhibit A.

**ANSWER:** Defendants Apotex Inc. and Apotex Corp. admit that the cover page of the '078 patent includes a title of "Aqueous Ophthalmic Formulations and Methods for Preserving Same," lists the inventors as Anthony Dziabo and Paul Ripley, and lists an issue date of June 13, 1995. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

11. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '078 patent.



**ANSWER:** Admitted that in conjunction with NDA No. 21-262 and 21-770, Allergan listed the '078, '873, '210, '337 and '834 patents. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

22. ALPHAGAN® P 0.15% and 0.10% are covered by at least one claim of each of the Listed Patents.

**ANSWER:** Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

23. On April 30, 2007, Allergan received a letter, dated April 26, 2007, signed on behalf of Apotex, Inc. The letter stated that Apotex had filed Abbreviated New Drug Application Nos. 78-479 and 78-480 ("ANDAs") with the United States Food and Drug Administration ("FDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market generic versions of Allergan's ALPHAGAN® P products, both the 0.15% and 0.10% formulations, before the expiration of the Listed Patents.

**ANSWER:** Admitted that Apotex Inc. sent a letter to Allergan on April 26, 2007; that the letter stated that Apotex Inc. had submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Products, Brimonidine Tartrate Ophthalmic Solution, 0.15% and Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA applications 78-479 and 78-480, before the expiration of the listed patents; otherwise denied.

24. The purpose of the April 26, 2007 letter was to notify Allergan that Apotex had filed a certification with the FDA under 21 C.F.R. § 314.50(i)(1)(i)(A)(4) ("Paragraph IV



certification”) in conjunction with its ANDAs. The letter alleged: (1) that the Listed Patents were invalid or unenforceable and (2) that, even if valid and enforceable, some claims of the Listed Patents would not be infringed by Apotex’s generic versions of Allergan’s ALPHAGAN® P products.

**ANSWER:** Admitted that the April 26, 2007 letter provided Allergan with notice that Apotex Inc. had filed a Paragraph IV certification with the FDA in conjunction with ANDA application nos. 78-479 and 78-480, admitted that the April 26, 2007 letter stated that the listed patents are invalid, unenforceable, and/or will not be infringed by Apotex’s manufacture, use, or sale of the Apotex Brimonidine Products, otherwise denied.

25. In filing its ANDAs, Apotex has requested the FDA’s approval to market generic versions of Allergan’s ALPHAGAN® P products throughout the United States, including Delaware.

**ANSWER:** Admitted that Apotex Inc. had submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex’s Proposed Products, Brimonidine Tartrate Ophthalmic Solution, 0.15% and Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA applications 78-479 and 78-480, throughout the United States, including Delaware; otherwise denied.

26. On information and belief, following FDA approval of its ANDAs, Apotex, Inc., through Apotex Corp., will sell the approved generic versions of Allergan’s ALPHAGAN® P products throughout the United States, including Delaware.

**ANSWER:** Admitted that if the FDA approves Apotex Inc.’s ANDA applications, it will seek to sell its approved Brimonidine Tartrate products throughout



the United States, and that it would be expected that such approved products would be sold by Apotex Inc., otherwise denied.

**COUNT I**

(Infringement of the '078 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

27. Paragraphs 1 to 26 are incorporated herein as set forth above.

**ANSWER:** Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

28. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271 (e)(2)(A).

**ANSWER:** Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.15% as defined in ANDA application 78-479. The remainder of the allegations are denied.

29. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '078 patent.

**ANSWER:** Denied.

**COUNT II**

(Infringement of the '873 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)



products for which approval is sought under ANDA applications 78-479 and 78-480 do not directly or indirectly infringe any valid claim of the '078, '873, '210, '337 and '834 patents.

**DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF**

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

- a. Finding that the '078, '873, '210, '377 and '834 patents are invalid and unenforceable;
- b. Finding that the '078, '873, '210, '377 and '834 patents are not infringed in any manner by either Apotex Inc. or Apotex Corp.;
- c. Finding that this is an exceptional case under 35 U.S.C. § 285;
- d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

**DEMAND FOR JURY TRIAL**

Apotex Inc. and Apotex Corp. demand a trial by jury on all issues appropriately tried to a jury.

OF COUNSEL:

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Robert B. Breisblatt  
James P. White  
Walter J. Kawula, Jr.  
Michael A. Krol  
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120 S. Riverside Plaza, 22nd Floor  
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Tel: (312) 655-1500

Dated: June 11, 2007  
800700 / 31920

POTTER ANDERSON & CORROON LLP

By: /s/ Richard L. Horwitz  
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*Attorneys for Defendants  
Apotex Inc. and Apotex Corp.*



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MEDPOINTE HEALTHCARE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 07-204-SLR
	)	
APOTEX INC. and APOTEX CORP.,	)	<b>JURY TRIAL DEMANDED</b>
	)	
Defendants.	)	

**DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S  
ANSWER, DEFENSES, AND COUNTERCLAIMS**

Defendants, Apotex Inc. and Apotex Corp., for their Answer, Defenses, and Counterclaims, to the complaint of MedPointe Healthcare Inc. ("Plaintiff" or "MedPointe"), state and allege as follows:

**PARTIES**

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

**ANSWER:** Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 1 of the Complaint, and therefore deny same.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

**ANSWER:** Admitted.

3. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

**ANSWER:** Admitted.



**NATURE OF THE ACTION**

9. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

**ANSWER:** Apotex Inc. and Apotex Corp. admit that MedPointe purports to bring an action under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, for the alleged infringement of United States Patent No. 5,164,194; otherwise denied.

**JURISDICTION AND VENUE**

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Admitted.

11. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. is a Delaware corporation.

**ANSWER:** Admitted that this Court has personal jurisdiction over Apotex Corp. for this action.

12. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware through its United States subsidiary and alter ego, Apotex Corp., which is a Delaware corporation; (2) its systematic and continuous contacts with Delaware, including its contacts with its United States subsidiary and alter ego and that entity's substantial and ongoing sale of numerous generic drugs in Delaware; (3) its performance of acts, either directly or through an agent, that have caused tortious injury in Delaware in connection with a persistent course of conduct with its United States subsidiary and alter ego; (4) its consent to personal jurisdiction in this Court in connection with another action for infringement of the '194 patent, Civil Action No. 06-164-SLR.

**ANSWER:** Denied, except to admit that this Court has personal jurisdiction over Apotex Inc. for this action.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d) and 1400(b).

**ANSWER:** Admitted.



**THE PATENT**

14. On November 17, 1992, the '194 patent, titled "AzelaStine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

**ANSWER:** Apotex Inc. and Apotex Corp. admit that the '194 patent, entitled "AzelaStine Containing Medicaments," was issued by the United States Patent and Trademark Office on November 17, 1992, that Asta Pharma AG is listed as the assignee, and that a document purporting to be a copy of the '194 patent is attached to the Complaint. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of paragraph 14, and therefore deny same. Defendants deny all other allegations in paragraph 14.

**ACTS GIVING RISE TO THIS ACTION**

15. Upon information and belief, on or about December 13, 2006, Apotex submitted ANDA 78-621 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

**ANSWER:** Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted ANDA 78-621 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) on or about December 13, 2006.

16. ANDA 78-621 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic ophthalmic solution product containing 0.05% azelaStine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal allergic rhinitis ("the Generic Product"). ANDA 78-621 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

**ANSWER:** Denied, except to admit that ANDA 78-621 seeks FDA approval to engage in the commercial manufacture, use, offer for sale and sale of a proposed drug



product as defined in ANDA 78-621 and that ANDA 78-621 specifically seeks FDA approval to market the proposed drug product prior to the expiration of the '194 patent.

17. ANDA 78-621 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written notification of ANDA 78-621 and its § 505(j)(2)(A)(vii)(IV) allegation on March 14, 2007.

**ANSWER:** The first sentence of paragraph 17 of the Complaint is admitted.

With regard to the second sentence in paragraph 17, Apotex Inc. and Apotex Corp. admit that Apotex Inc. sent written notification of ANDA 78-621 to MedPointe on or about March 12, 2007.

18. Upon information and belief, consistent with its practice with respect to other generic products, Apotex Inc. has designated Apotex Corp. as its agent in the United States for purposes of filing ANDA 78-621 and for marketing and selling the Generic Product in the United States upon any approval of ANDA 78-621.

**ANSWER:** Apotex Inc. and Apotex Corp. admit that Apotex Corp. markets and sells generic drug products manufactured by Apotex Inc. throughout the United States following FDA approval. Apotex Inc. and Apotex Corp. further admit that in ANDA 78-621 filed by Apotex Inc., Apotex Inc. designated Apotex Corp. as its agent in the United States for all matters related to ANDA 78-621; otherwise denied.

19. Apotex's submission of ANDA 78-621 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

**ANSWER:** Denied.

20. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '194 patent.



**DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF**

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

- a. Finding that the '194 patent is invalid and unenforceable;
- b. Finding that the '194 patent is not infringed in any manner by either Apotex Inc. or Apotex Corp.;
- c. Finding that this is an exceptional case under 35 U.S.C. § 285;
- d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

**DEMAND FOR JURY TRIAL**

Apotex Inc. and Apotex Corp. demand trial by jury for all issues triable by jury.

This demand is contingent upon MedPointe seeking monetary damages as set forth in paragraph D of its prayer for relief in its complaint.

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Apotex Corp.*



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MEDPOINTE HEALTHCARE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-164 (SLR)
	)	
APOTEX INC. and APOTEX CORP.,	)	<b>JURY TRIAL DEMANDED</b>
	)	
Defendants.	)	

**ANSWER OF APOTEX INC. AND APOTEX CORP. TO  
PLAINTIFF'S AMENDED COMPLAINT, AFFIRMATIVE DEFENSES  
AND COUNTERCLAIMS**

Defendants, Apotex Inc. and Apotex Corp., Answer the Amended Complaint of Plaintiff, MedPointe Healthcare Inc., as follows:

**PARTIES**

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

**ANSWER:** Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of these averments in this paragraph.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

**ANSWER:** Admit that Apotex, Inc. is a corporation organized and existing under the laws of Canada and having a place of business at 380 Elgin Hills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

3. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.



8. Upon information and belief, Apotex Corp. is the United States subsidiary and alter ego of Apotex Inc. Upon information and belief, for purposes of this action, Apotex Inc. and Apotex Corp. are effectively the same entity and are referred to collectively hereinafter as Apotex.

**ANSWER:** Deny, except to admit that Apotex Inc. and Apotex Corp. are related companies and that Plaintiff may refer to them collectively as Apotex even though they are separate entities.

#### **NATURE OF THE ACTION**

9. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*

**ANSWER:** This paragraph contains MedPointe's characterization of its action and to which no answer is required, but insofar as an answer is required, deny.

#### **JURISDICTION AND VENUE**

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Admit.

11. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. is a Delaware corporation.

**ANSWER:** Admit.

12. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware through its United States subsidiary and alter ego, Apotex Corp., which is a Delaware corporation; (2) its systematic and continuous contacts with Delaware, including its contacts with its United States subsidiary and alter ego and that entity's substantial and ongoing sale of numerous generic drugs in Delaware; and (3) its performance of acts, either directly or through an agent, that have caused tortious injury in Delaware in connection with a persistent course of conduct with its United States subsidiary and alter ego.

**ANSWER:** Deny, except to admit that this Court has personal jurisdiction over Apotex, Inc. for this matter.



13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d) and 1400(b).

**ANSWER:** Apotex admits that venue in this district is proper for this action

#### **THE PATENT**

14. On November 17, 1992, the '194 patent, titled "Azelastine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

**ANSWER:** Deny that the '194 patent was duly and legally issued on November 17, 1992. Admit that a document purporting to be U.S. Patent Number 5,164,194 was attached to the Complaint, and that Asta Pharma AG is listed thereon as assignee. With regard to the remaining allegations, Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of these averments, which has the effect of denial reasonably based on lack of information and belief.

#### **ACTS GIVING RISE TO THIS ACTION**

15. Upon information and belief, on or about November 14, 2005, Apotex submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

**ANSWER:** Deny, expect to admit that Apotex Inc. submitted ANDA 077954 to the FDA under §505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 335) on or about November 14, 2005.

16. ANDA 77-954 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic nasal spray product containing 0.1% azelastine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal rhinitis ("the Generic Product"). ANDA 77-954 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.



**ANSWER:** Admit that ANDA 77-954 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a nasal spray product containing 0.1% azelastine hydrochloride in an aqueous solution having the name Azelastine Hydrochloride Nasal Spray (the “proposed product”) for use in treating, *inter alia*, seasonal rhinitis, and that ANDA 77-954 specifically seeks FDA approval to market the proposed drug product prior to the expiration of the ’194 patent. The remaining allegations are denied.

17. ANDA 77-954 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the ’194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written Notification of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation on January 27, 2005.

**ANSWER:** Admit that ANDA 77-954 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the ’194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the proposed drug product. Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining averments, which has the effect of denial reasonably based on lack of information and belief.

18. In the written notification of ANDA 77-954, Apotex Inc. designated Apotex Corp. as its “agent in the United States authorized to accept service of process for Apotex.”

**ANSWER:** Admit that in the written notification of ANDA 77-954, Apotex Inc. designated Apotex Corp. as its “agent in the United States authorized to accept service of process for Apotex.”

19. Upon information and belief, and consistent with its practice with respect to other generic products, Apotex Inc. has designated Apotex Corp. as its agent in the



United States for purposes of filing ANDA 77-954 and for marketing and selling the Generic Product in the United States upon any approval of ANDA 77-954.

**ANSWER:** Deny, except to admit that Apotex Inc. has designated Apotex Corp. as its agent in the United States in ANDA 77-954 to the extent required by FDA regulations and for service of legal process.

20. Apotex's submission of ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

**ANSWER:** Admit that Apotex Inc. submitted ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation. All other averments of this paragraph are denied.

21. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '194 patent.

**ANSWER:** Deny.

22. Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. This is so because, upon information and belief, Apotex Inc. submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and will, *inter alia*, manufacture, offer to sell and sell the Generic Product upon receipt of any FDA approval of ANDA 77-954.

**ANSWER:** Deny that Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. Admit that Apotex Inc. submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and intends to, *inter alia*, manufacture the proposed drug product upon receipt of FDA approval of ANDA 77-954.

23. Apotex Inc.'s submission of ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35



U.S.C. §271(e)(2)(A). Moreover, if Apotex Inc. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

**ANSWER:** Admit that Apotex Inc. submitted ANDA 77-954 to the FDA, including the §505(j)(2)(A)(vii)(IV) allegation. All other averments of this paragraph are denied.

24. Apotex Corp. is jointly and severally liable for the infringement of the '194 patent, regardless of which Apotex entity actually filed ANDA 77-954 and regardless of whether it is treated as the alter ego of Apotex Inc. for purposes of this action. This is so because, upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA and will, *inter alia*, offer to sell and sell the Generic Product within the United States and this judicial district upon receipt of any FDA approval of ANDA 77-954.

**ANSWER:** Deny, except to admit that if ANDA 77-954 is approved, it is expected that Apotex Corp. would offer to sell and sell the proposed drug product in the United States.

25. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '194 patent under 35 U.S.C. § 271 (e)(2)(A). Moreover, if Apotex Corp. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

**ANSWER:** Deny.

26. Apotex had actual and constructive notice of the '194 patent prior to filing ANDA 77-954.

**ANSWER:** Deny, except to admit that Apotex Inc. and Apotex Corp. had access to the FDA Orange Book which listed the '194 patent.

27. MedPointe will be irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. MedPointe does not have an adequate remedy at law.



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*Attorneys for Defendants  
Apotex Inc. and Apotex Corp.*



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	<b>JURY TRIAL DEMANDED</b>
	)	
Defendant.	)	

**DEFENDANT APOTEX, INC.'S ANSWER,  
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant, Apotex, Inc. ("Defendant" or "Apotex"), for its Answer, Affirmative Defenses, and Counterclaim, to the complaint of Merck & Co., Inc. ("Plaintiff" or "Merck"), states and alleges as follows:

**THE PARTIES**

1. Plaintiff Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck drive, Whitehouse Station, New Jersey 08889.

**ANSWER:** Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

2. On information and belief, Defendant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. It has authorized Apotex Corp., incorporated under the laws of Delaware and with principal place of business at 2400 North Commerce Parkway, Suite 400 Weston, Florida 33326, to act as agent for service of process with respect to commencement of this patent infringement action.

**ANSWER:** Admitted.

**JURISDICTION AND VENUE**

3. This action arises under the patent laws of the United States of America and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).



**ANSWER:** Apotex admits that Merck purports to bring an action under the patent laws of the United States of America and admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); otherwise denied.

4. Venue is proper in this court under Title 28, United States Code §§ 1391(c) and 1400(b), because the defendant has submitted to personal jurisdiction in this judicial district for this action.

**ANSWER:** Admitted.

### **BACKGROUND**

5. On October 25, 1994, United States Letters Patent No. 5,358,941 (the “‘941 patent”), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS WITH LACTOSE, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The ‘941 patent is currently set to expire on December 2, 2012. The ‘941 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget’s disease, malignant hypercalcemia, and metastatic bone disease. A copy of the ‘941 patent is attached to this Complaint as Exhibit 1.

**ANSWER:** Apotex admits that United States Patent No. 5,358,941, entitled “Dry Mix Formulation For Bisphosphonic Acids With Lactose” was issued by the United States Patent and Trademark Office on October 25, 1994 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the ‘941 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

6. On October 28, 1997, United States Letters Patent No. 5,681,590 (the “‘590 patent”), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The ‘590 patent is currently set to expire on December 2, 2012. The ‘590 patent discloses and claims novel pharmaceutical compositions and novel processes for manufacturing compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget’s disease, malignant hypercalcemia, and metastatic bone disease. A copy of the ‘590 patent is attached to this Complaint as Exhibit 2.



pediatric studies pursuant to 21 U.S.C. § 355a(c). This six-month period is also listed in the Orange Book. The FDA may therefore not approve to market generic versions of Merck's FOSAMAX<sup>®</sup> tablets until six months after the expiration date of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. The six-month "pediatric exclusivity period" expires on June 2, 2013, for the '941 patent; June 2, 2013, for the '590 patent; December 6, 2015, for the '726 patent; December 6, 2015, for the '207 patent; June 2, 2013, for the '410 patent; June 2, 2013, for the '004 patent; January 17, 2019, for the '329 patent; January 17, 2019, for the '801 patent; and January 17, 2019, for the '294 patent. The FDA also may not approve to market generic versions of Merck's FOSAMAX<sup>®</sup> tablets until the expiration of all other patents and the subsequent pediatric exclusivity period listed in the Orange Book.

**ANSWER:** Apotex admits that the Orange Book shows the pediatric exclusivity period for the patents as stated in the averments in this paragraph and Apotex denies the remaining averments in this paragraph.

17. On information and belief, an Abbreviated New Drug Application (ANDA No. 077-982) has been filed on behalf of Apotex, including a certification under Title 21, United States Code § 355(j)(2) with the FDA for 5 mg, 10 mg, 35 mg, and 70 mg alendronate sodium tablets. Apotex's ANDA No. 077-982 allegedly contains a certification of invalidity, unenforceability, and/or noninfringement of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. Notice of that certification, but not the certification, was transmitted to Merck on or after February 24, 2006.

**ANSWER:** Admitted.

18. On information and belief, Apotex filed ANDA No. 077-982 because it seeks to enter the market that FOSAMAX<sup>®</sup> pharmaceutical products have created due to their benefits and advantages.

**ANSWER:** Denied, except to admit that Apotex seeks permission from the FDA to sell a generic version of Fosamax<sup>®</sup>.

### **COUNT I**

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

**ANSWER:** Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

20. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '941 patent, before the expiration of the '941 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).



I hereby certify that on May 9, 2006, I have Federal Expressed the attached document to the following non-registered participants:

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728942



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

TORPHARM, INC., APOTEX CORP.,  
and APOTEX, INC. )

Plaintiffs, )

v. )

PFIZER INC., and WARNER-  
LAMBERT COMPANY (n/k/a  
WARNER-LAMBERT LLC) )

Defendants. )

Civil Action No. 03 - 990

COMPLAINT FOR DECLARATORY JUDGMENT  
AND DEMAND FOR JURY TRIAL

The Plaintiffs, TorPharm, Inc., Apotex Corp., and Apotex, Inc. (collectively "TorPharm"), for their Complaint against Defendants Pfizer Inc. and Warner-Lambert Company (n/k/a Warner-Lambert LLC) (collectively "Pfizer"), allege as follows:

**Nature Of The Action**

1. This action for declaratory judgment of patent noninfringement arises, *inter alia*, out of TorPharm's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Pfizer's blockbuster drug Accupril® (quinapril hydrochloride). FDA approval of TorPharm's ANDA is imminent.
2. Pfizer owns U.S. Patent No. 4,743,450 ("the '450 patent"), which discloses and claims, *inter alia*, a quinapril pharmaceutical composition. Pfizer has listed the '450 patent in the FDA's "Orange Book" and, as a consequence, maintains that the '450 patent claims the approved drug, Accupril® (quinapril hydrochloride), and that a claim for patent infringement



could reasonably be asserted against any ANDA applicant attempting to market a generic quinapril product. Pfizer, moreover, has enforced and continues to vigorously enforce its intellectual property rights on blockbuster drugs against TorPharm and others, and has already sued and obtained a judgment of infringement on the '450 patent against another generic quinapril applicant.

3. TorPharm has designed around the '450 patent with its proposed quinapril product and so, as required by statute, has certified to the FDA that its product will not infringe the '450 patent and further notified Pfizer of the legal and factual bases for that certification. TorPharm's certification to the '450 patent constitutes a technical or artificial act of infringement under the Hatch-Waxman Act putting TorPharm at considerable risk of being sued by Pfizer both before and after market entry. Pfizer has not yet responded to the submission of TorPharm's ANDA and certification that TorPharm does not infringe. Moreover, Pfizer has not informed TorPharm that TorPharm does not infringe the '450 patent and has not covenanted not to sue TorPharm for infringement of the '450 patent.

4. On information and belief, Pfizer believes that a claim for infringement could be reasonably asserted against TorPharm and Pfizer intends to sue TorPharm for infringement of the '450 patent. There is an actual, substantial, and continuing justiciable case and controversy between TorPharm and Pfizer regarding infringement of the '450 patent, for which this Court can declare the rights of the parties. TorPharm is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril product does not and will not infringe the '450 patent.



### The Parties

5. Plaintiff TorPharm, Inc. is a corporation duly organized and existing under the laws of Canada and having its principal place of business in Etobicoke, Ontario, Canada. TorPharm develops, manufactures and markets generic drugs, and in particular solid oral dosage forms such as capsules and tablets, for sale and use in the United States following FDA approval.

6. Plaintiff Apotex Corp. is a corporation incorporated and existing under the laws of the State of Delaware, having a place of business at 616 Heathrow Drive, Lincolnshire, Illinois 60069. Apotex Corp. is the United States marketing and sales affiliate for TorPharm. Following FDA approval of an ANDA, TorPharm manufactures and supplies generic drug products to Apotex Corp., which then markets and sells those products to large wholesalers, warehousing chains, mail order organizations, and distributors in the United States. Apotex Corp. also acts as TorPharm's U.S. agent for purposes of making regulatory submissions, including ANDAs, to the FDA.

7. Plaintiff Apotex Inc. is a corporation organized and existing under the laws of Canada and having its principal place of business at 150 Signet Drive, Weston, Ontario, Canada M9L 1T9.

8. Plaintiffs TorPharm, Inc., Apotex Corp., and Apotex, Inc. are collectively referred to in this Complaint as "TorPharm."

9. On information and belief, Defendant Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York, 10017-5575.

10. On information and belief, Defendant Warner-Lambert Company was or is a Delaware corporation with a place of business at 201 Tabor Road, Morris Plains, New Jersey 07950. On information and belief, Warner-Lambert Company became a wholly-owned



subsidiary of Pfizer Inc. as of June 19, 2000. On information and belief, Warner-Lambert Company subsequently became Warner-Lambert LLC, a limited liability company incorporated under the laws of the State of Delaware, having its principal place of business at 201 Tabor Road, Morris Plains, New Jersey 07950.

11. Defendants Pfizer Inc. and Warner-Lambert Company are collectively referred to in this Complaint as "Pfizer."

#### Jurisdiction And Venue

12. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

13. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*

14. There exists a substantial and continuing actual, justiciable case or controversy between TorPharm and Pfizer regarding infringement of the '450 patent.

15. This Court may declare the rights and legal relations of the parties regarding noninfringement of the '450 patent pursuant to, *inter alia*, 28 U.S.C. §§ 2201, 2202.

16. This Court has personal jurisdiction over Pfizer Inc. and Warner-Lambert Company (n/k/a Warner-Lambert LLC) because they both reside and are located in this District and because they both conduct substantial business in, and have regular and systematic contact with, this District.

17. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).



**Statutory Scheme For Approval Of New And Generic Drugs**

18. The approval of new and generic drugs is governed by the applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman").

***New drugs and patent listing requirements***

19. Before marketing an original new drug (*i.e.*, not a generic drug) in the United States, Hatch-Waxman requires that an applicant submit, and that FDA approve, a new drug application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested.

20. An NDA applicant is required, within its NDA, to submit information (*i.e.*, *inter alia*, the patent number and expiration date) regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1).

21. FDA publishes patent information submitted by an NDA-holder in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

22. By filing an NDA and listing a patent in the Orange Book, the NDA-holder and/or patentee, by law, necessarily maintains that the listed patent claims the approved NDA drug and



that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, sale or use of the drug.

23. In other words, the NDA-holder and/or patentee necessarily puts all prospective generic ANDA-filers on notice that a suit for infringement can and will be asserted against any ANDA-filer that attempts to seek approval for and market a generic version of the NDA drug.

24. Such conduct by the NDA-holder and/or patentee gives rise to a reasonable apprehension on the generic applicant's part that it will face an infringement suit or the threat of one if it attempts to seek approval for or to market a generic version of the NDA drug.

*Generic drugs and patent certification requirements*

25. Hatch-Waxman provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-cost generic versions of previously approved brand-name or NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. The ANDA process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.

26. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already approved NDA drug by submitting an ANDA to the FDA under 21 U.S.C. § 355(j).

27. Instead of repeating the comprehensive, extensive human studies conducted for the previously approved NDA drug, a generic applicant submitting an ANDA is only required to establish, among other details, that its proposed generic product is bioequivalent to the already approved NDA drug (*i.e.*, has no significant difference in rate and extent of absorption) and that



it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling (with certain exceptions) as the approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

28. An ANDA applicant is also required to address each patent listed in the Orange Book in connection with the approved NDA drug. In particular, Hatch-Waxman requires an ANDA applicant to submit one of four types of patent certifications for each listed patent: (I) that the NDA-holder has not submitted any patent information to FDA; (II) that the listed patent(s) has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date (commonly referred to as a "paragraph III certification"); or, (IV) that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic product prior to expiration of the subject patent.

29. When an ANDA applicant submits a paragraph IV certification for a listed patent, the generic applicant must notify the NDA-holder and the patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent (indicating that the ANDA applicant intends to market its generic product before expiration of the listed patent). 21 U.S.C. § 355(j)(2)(B). This notice must contain a detailed statement of the factual and legal basis for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(ii).



30. The submission of a paragraph IV certification for a listed patent constitutes an artificial or technical act of infringement that creates the necessary subject matter jurisdiction to enable a patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

31. Upon receipt of the notice of the paragraph IV certification for the listed patent submitted by the ANDA applicant, the NDA-holder/patent owner may file suit for infringement of the listed patent under 35 U.S.C. § 271(e)(2)(A) within forty-five (45) days of receiving such notification.

32. Congress enacted Hatch-Waxman and the ANDA approval process in order to expedite the marketing of generic drug products.

33. Congress intended that the generic manufacture and marketing of a drug should be allowed as soon as it is determined that the particular drug does not violate patent rights, and should not be delayed just because the patentee has not sued the generic applicant first, but rather has merely held its patents over the generic applicant like a modern-day “Sword of Damocles.”

34. Congress therefore contemplated that ANDA-filers must obtain a favorable court decision on the patent in order to market the generic drug. This can be accomplished by either being sued by the NDA-holder/patentee within the 45-day period or by the generic ANDA-filer seeking a declaratory judgment of patent infringement and/or invalidity.

35. An ANDA-filer is statutorily prohibited from seeking a declaratory judgment during the 45-day period in which the NDA-holder may bring suit after receiving notification of the ANDA and paragraph IV certification. Congress, however, clearly intended that a



declaratory judgment action be available for ANDA-filers who are not sued by the NDA patentee within the 45-day period.

36. The acts of an NDA-holder/patentee listing a patent in the Orange Book through the filing of an NDA and a generic manufacturer filing an ANDA together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement and/or invalidity.

**Pfizer's Accupril® (Quinapril Hydrochloride)**

37. On information and belief, Pfizer Inc. is the holder of approved NDA No. 19-885 for quinapril hydrochloride tablets, which are sold under the brand-name Accupril®.

38. Accupril® (quinapril hydrochloride) is indicated for the treatment of hypertension and as adjunctive therapy in the management of heart failure.

39. On information and belief, Warner-Lambert Company purports and claims to be the owner of U.S. Patent No. 4,743,450 ("the '450 patent"), the term of which expires on or about August 24, 2007. The '450 patent recites a quinapril pharmaceutical formulation containing a metal-containing stabilizer and a saccharide which minimize the cyclization, hydrolysis and coloration of certain ACE inhibitors, including quinapril. A true and correct copy of the '450 patent is attached to this Complaint as Exhibit A.

40. On information and belief, Pfizer purports and claims to have the right to enforce the '450 patent.

41. Pfizer submitted information on the '450 patent to FDA for placement in the Orange Book. By virtue of that submission, the FDA listed the '450 patent in the Orange Book in connection with Pfizer's approved NDA for Accupril® (quinapril hydrochloride) tablets.



42. By listing the '450 patent in the Orange Book, Pfizer maintains that the '450 patent claims Accupril® (quinapril hydrochloride) tablets and that an infringement suit could reasonably be asserted against any generic ANDA-filer that attempts to seek approval for and market a generic version of quinapril.

**TorPharm's ANDA For Quinapril Hydrochloride Tablets**

43. On September 13, 2001, TorPharm submitted an ANDA to the FDA seeking approval to market a generic version of Accupril® (quinapril hydrochloride) tablets in 5 mg, 10 mg, 20 mg, and 40 mg strengths. That ANDA was received by the FDA on September 20, 2001 and was assigned ANDA number 76-240 by the FDA ("ANDA No. 76-240").

44. TorPharm's ANDA sought permission to market quinapril hydrochloride tablets for the treatment of hypertension and as adjunctive therapy in the management of heart failure.

45. As part of its ANDA No. 76-240, TorPharm submitted a paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), certifying to FDA that the '450 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of TorPharm's quinapril hydrochloride tablets.

46. On information and belief, the FDA's review of TorPharm's ANDA No. 76-240 will be completed in the near future and approval is imminent.

47. TorPharm intends and is prepared to market its generic quinapril product before expiration of the '450 patent.

48. On or about November 15, 2001, in accordance with 21 U.S.C. §§ 355(j)(2)(B)(i),(ii), TorPharm provided Pfizer with notice that it submitted a quinapril ANDA and a paragraph IV certification to the '450 patent. This notice included a detailed statement setting forth the factual and legal bases why the '450 patent will not be infringed by the



manufacture, use, offer for sale, sale, or importation of TorPharm's quinapril hydrochloride tablets.

**Pfizer's Litigious Conduct And Vigorous Enforcement  
Of Its Intellectual Property Rights**

49. Pfizer has a long history and program of vigorously enforcing its patents against generic drug applicants, including TorPharm.

50. For example, Pfizer (and its predecessors) have sued numerous ANDA-filers for alleged infringement of patents covering its blockbuster drug Zoloft®. (*Pfizer v. Zenith Goldline Pharms., Inc.*, 00-CV-0408 (D.N.J.)).

51. Pfizer (and its predecessors) have also sued ANDA-filers for alleged infringement of patents covering its blockbuster drug Norvasc®, (*Pfizer v. Dr. Reddy's Labs.*, 02-CV-2829 (D.N.J.)).

52. Pfizer (and its predecessors) also filed suit against a generic competitor regarding Pfizer's drug Procardia XL® (nifedipine). (*Bayer AG, et al. v. Mylan Labs.*, 97-CV-1309 (W.D. Pa.)).

53. Similarly, Pfizer (and its predecessors) have sued ANDA-filers for alleged infringement of patents covering Pfizer's drug Glucotrol XL® (glipizide). (*Pfizer Inc. v. Andrx Corp.*, 01-CV-3260 (D.N.J.)).

54. Pfizer (and its predecessors) also sought to protect its drug Diflucan® (fluconazole) from generic competition by filing suit against ANDA-filers. (*Pfizer Inc. v. Novopharm Ltd.*, 00-CV-1475 (N.D. Ill.)).

55. Pfizer (and its predecessors) have further sued at least eight ANDA-filers, including TorPharm, in numerous Districts for alleged infringement of three patents purportedly covering Pfizer's drug Neurontin® (gabapentin). (*In re Gabapentin Patent Litig.*, MDL No. 1384



(D.N.J.); *Pfizer Inc. v. Apotex Corp.*, 01-CV-611 (D.N.J.); *Pfizer Inc. v. Apotex Corp.*, 00-CV-4398 (N.D. Ill.); *Warner-Lambert Co. v. Apotex Corp.*, 98-CV-4293 (N.D. Ill.); *Pfizer Inc. v. Pharm. Holdings Corp.*, 03-CV-740 (E.D. Pa.); *Pfizer Inc. v. Geneva Pharms., Inc.*, 03-CV-1545 (D.N.J.); *Pfizer Inc. v. Ranbaxy Pharms., Inc.*, 03-CV-1824 (D.N.J.)).

56. Indeed, as recently as October 7, 2003, Pfizer stated that it intends to aggressively defend its intellectual property. Found at [http://www.pfizer.com/arc/news\\_releases](http://www.pfizer.com/arc/news_releases).

#### **Quinapril Hydrochloride Litigation**

57. Pfizer has further demonstrated a willingness and intention to enforce the '450 patent against similarly-situated generic pharmaceutical companies that have filed an ANDA to market generic quinapril hydrochloride.

58. Pfizer has filed suit against one of TorPharm's competitors in *Warner-Lambert v. Teva Pharms. USA, Inc.*, 99-CV-0922 (D.N.J.), alleging infringement of the '450 patent. The district court in New Jersey recently granted Pfizer a summary judgment of infringement against Teva regarding the '450 patent.

59. Pfizer recently noted that the court decision on the '450 patent "affirms positions that [Pfizer] has taken with respect to the Accupril patent from the very beginning of the litigation." Found at [http://www.pfizer.com/arc/news\\_releases](http://www.pfizer.com/arc/news_releases).

#### **There Is A Substantial And Continuing Justiciable Controversy Between TorPharm And Pfizer Regarding Infringement Of The '450 Patent**

60. By preparing and filing TorPharm's ANDA No. 76-240, TorPharm has substantially prepared to make, use, import, offer to sell, and sell quinapril hydrochloride tablets in the United States.

61. By submitting its ANDA No. 76-240 to engage in the commercial manufacture, use, offer for sale, sale, or importation of quinapril hydrochloride tablets before the expiration of



the '450 patent, as well as filing a paragraph IV certification to the '450 patent, TorPharm has committed an act that may be viewed as an artificial or technical act of infringement sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2)(A).

62. By submitting the '450 patent to the FDA for listing in the Orange Book, Pfizer has indicated that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." See 21 U.S.C. § 355(b)(1). In other words, Pfizer necessarily maintains that an infringement claim on the '450 patent could be reasonably asserted against any generic quinapril applicant, including TorPharm.

63. Pfizer did not sue TorPharm for infringement of the '450 patent within forty-five (45) days of receipt of TorPharm's notice of paragraph IV certification. As such, a declaratory judgment action is available to TorPharm.

64. Pfizer has never communicated to TorPharm that TorPharm does not infringe or that Pfizer does not intend to bring a lawsuit against TorPharm for infringement of the '450 patent.

65. Pfizer has demonstrated a willingness and, further, an intention to enforce its '450 patent against similarly situated quinapril hydrochloride ANDA-filers. Also, just three weeks ago and after a favorable summary judgment award regarding the '450 patent, Pfizer made public representations that the decision is in line with Pfizer's beliefs regarding Accupril® (quinapril hydrochloride) and that Pfizer intends to continue aggressively defending its intellectual property.

66. Based upon, *inter alia*, Pfizer's listing of the '450 patent and implicit assertions that an infringement claim could be brought against any generic quinapril applicant; TorPharm's ANDA with a paragraph IV certification to the '450 patent and technical or artificial act of



infringement; TorPharm's intention to market its generic quinapril product before expiration of the '450 patent; Pfizer's failure to state that TorPharm does not infringe the '450 patent or covenant that it will not sue TorPharm for infringement of the '450 patent; Pfizer's suits against similarly situated third-parties concerning the '450 patent; Pfizer's public statements that it will continue to aggressively defend challenges to its intellectual property; Pfizer's (and its predecessors') pattern of aggressively enforcing its patents against TorPharm specifically and the generic pharmaceutical industry generally; and Pfizer's recent summary judgment of infringement regarding the '450 patent, TorPharm is under a reasonable apprehension that Pfizer will sue TorPharm alleging infringement of the '450 patent. Such a reasonable apprehension creates an actual controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

67. To avoid legal uncertainty, to protect its substantial investment, and to protect its anticipated future investments in its manufacturing process for TorPharm's quinapril hydrochloride tablets, TorPharm has instituted this action and is entitled to a declaration of the rights of the parties with respect to the '450 patent.

#### **Declaratory Judgment Of Noninfringement**

68. TorPharm asserts and realleges paragraphs 1 through 67 above as if fully set forth herein.

69. TorPharm has already committed what may constitute a technical or artificial act of infringement by submitting its ANDA with an accompanying paragraph IV certification. TorPharm has also produced an allegedly infringing quinapril product and intends and is prepared to market that product before expiration of the '450 patent.



70. Pfizer has engaged, and continues to engage, in conduct giving rise to a reasonable and objective apprehension on TorPharm's part that TorPharm will face an infringement suit if it commences marketing of its generic quinapril product.

71. There is an actual, substantial, and continuing justiciable case and controversy between TorPharm and Pfizer regarding infringement of the '450 patent.

72. The manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent.

73. TorPharm is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent.

#### **Prayer For Relief**

WHEREFORE, TorPharm respectfully prays for judgment in its favor and against Pfizer:

- (a) Declaring that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent; and
- (b) Awarding TorPharm its reasonable attorneys' fees and costs of this action; and,



- (c) Awarding TorPharm such other and further relief as the Court may deem just and proper.

**Jury Demand**

The Plaintiffs, TorPharm, Inc., Apotex Corp., and Apotex, Inc., hereby demand a trial by jury on all issues so triable.

ASHBY & GEDDES



Steven J. Balick (L.D. # 2114)  
John G. Day (L.D. # 2403)  
222 Delaware Avenue, 17th Floor  
P.O. Box 1150  
Wilmington, Delaware 19899  
Telephone: (302) 654-1888  
Facsimile: (302) 654-2067

*Attorneys for Plaintiffs, TorPharm, Inc.,  
Apotex Corp., and Apotex, Inc.*

*Of Counsel:*

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Dated: October 29, 2003  
134300.1



# **EXHIBIT H**



**KIRKLAND & ELLIS LLP**  
AND AFFILIATED PARTNERSHIPS

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December 6, 2007

**By Federal Express**  
**and Electronic Mail**

Dr. Bernard Sherman  
Chairman & C.E.O.  
Apotex Inc.  
150 Signet Drive  
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bsherman@apotex.com

Tammy McIntyre  
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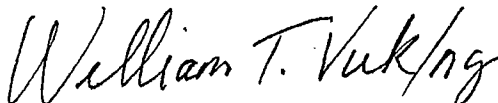
**Re: Apotex Inc.'s ANDA 79-013**

Dear Dr. Sherman and Ms. McIntyre:

Enclosed are (1) a courtesy copy of the Complaint filed today by sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") against Apotex Inc. and Apotex Corp. (collectively "Apotex") in the United States District Court for the District of Delaware, and (2) copies of two Complaints from related cases previously filed by sanofi-aventis in the District of Delaware with respect to other generic challengers of Uroxatral®.

Please let me know by noon on Monday December 10, 2007 if Apotex will consent to jurisdiction in Delaware.

Sincerely,

  
William T. Vuk

enclosures

cc by email:

Bernice Tao (btao@apotex.com)  
Apotex Inc.

Jack Blumenfeld, Esq.  
Morris Nichols Arsht & Tunnell



# **EXHIBIT I**



---

**From:** Noreika, Maryellen  
**Sent:** Tuesday, December 11, 2007 4:30 PM  
**To:** 'srollo@welshkatz.com'  
**Subject:** sanofi v. Apotex

Dear Sherry --

This will confirm our earlier discussion that 1) the Apotex defendants will not contest jurisdiction in the District of Delaware in the litigation -- *sanofi-aventis, et al. v. Apotex Inc., et al.*, C.A. No. 07-792 (D. Del) -- and 2) plaintiffs will consent to Apotex's request for a 14 day extension to respond to the complaint. I will draft a stipulation regarding the extension for your review.

Maryellen Noreika

---

This message, including any accompanying documents or attachments, may contain information that is confidential or that is privileged. If you are not the intended recipient of this message, please note that the dissemination, distribution, use or copying of this message or any of the accompanying documents or attachments is strictly prohibited. If you believe that you may have received this message in error, please contact me at (302) 658-9200 or by return e-mail.



# **EXHIBIT J**



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302 658 3989 FAX

MARYELLEN NOREIKA  
302 351 9278  
302 425 3011 FAX  
mnoreika@mnat.com

December 31, 2007

Sherry L. Rollo, Esquire  
WELSH & KATZ, LTD.  
120 South Riverside Plaza  
Chicago, IL 60606-3912

VIA ELECTRONIC MAIL

Re: *sanofi-aventis et al v. Apotex Inc. et al*,  
C.A. No. 07-792-GMS

Dear Sherry:

On December 11, 2007, you agreed that the Apotex defendants would not contest jurisdiction in the District of Delaware. Despite your agreement, in the answer filed in Florida, Apotex now denies that the Delaware court has personal jurisdiction over Apotex Inc. Please let me know the basis on which Apotex has denied that there is personal jurisdiction over Apotex Inc. in Delaware after you agreed that defendants would not challenge jurisdiction in Delaware.

Sincerely,

  
Maryellen Noreika

cc: Richard L. Horwitz, Esquire  
Gerald J. Flattmann, Esquire



# **EXHIBIT K**



**WELSH & KATZ, LTD.**

*Attorneys at Law*

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Direct Dial (312) 526-1551

January 7, 2008

**Via Electronic Mail (wvuk@kirland.com) &  
Confirmation by U.S. Mail**

William T. Vuk, Esq.  
Kirkland & Ellis LLP  
Citigroup Center  
153 East 53<sup>rd</sup> Street  
New York, New York 10022-4611

**Re: *Sanofi-Aventis et al. v. Apotex Inc. et al.*  
Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)**

Dear William:

We acknowledge receipt of your January 4, 2008 correspondence. We do not agree to transfer the above-captioned case to Delaware. Nor do we agree to a stay of the Florida action pending resolution of any motions to transfer. Sanofi is obligated under the Hatch-Waxman Act to "reasonably cooperate in expediting the action." *E.g.*, 21 U.S.C. § 355(j)(5)(B)(iii). Therefore, we believe that Sanofi should dismiss its Delaware lawsuit against our clients in favor of the Florida action, which necessarily will proceed more quickly to resolution. Please let us know whether your client will agree to dismissal of the Delaware complaint.

I am available this afternoon (after 2pm (CST)) to discuss this and other issues related to the Court's scheduling order.

Very truly yours,

WELSH & KATZ, Ltd.

By:   
Steven E. Feldman

SEF/mh

cc: Alfred J. Saikali, Esq. (asikali@shb.com)  
Stephen J. Bronis, Esq. (sbronis@zuckerman.com)  
Robert B. Breisblatt, Esq. (rbbreisblatt@welshkatz.com)  
Sherry L. Rollo, Esq. (srollo@welshkatz.com)



# **EXHIBIT L**



## KIRKLAND & ELLIS LLP

AND AFFILIATED PARTNERSHIPS

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Facsimile:  
212 446-4900

January 7, 2008

**By Electronic Mail**

Steven E. Feldman, Esq.  
Welsh & Katz, LTD.  
120 South Riverside Plaza  
Chicago, Illinois 60606  
sefeldman@welshkatz.com

Re: *Sanofi-aventis et al. v. Apotex Inc. et al.*,  
C.A. No. 07-792 (GMS)  
Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Steven:

I write to memorialize our meet and confer discussion from earlier today related to the above matters.

In light of sanofi-aventis's first-filed Delaware action, sanofi-aventis requested that the parties meet and confer on the disposition of the second-filed Florida action in an attempt to avoid any unnecessary motion practice before the Court. Specifically, we asked that Apotex agree to the dismissal of the Florida action, transfer to Delaware, or stay pending the disposition of any venue issues in Delaware. Because Apotex has refused to agree that the identical claims and counterclaims of the Delaware and Florida actions should proceed in Delaware along with sanofi-aventis's claims against 13 other defendants, we are left with no choice but to seek relief from the Court.

The following summary confirms the results of the parties' meet and confer today. Please let me know if there is anything you disagree with.

**Dismissal or Stay of Claims/Counterclaims Pending In Florida:** You confirmed that Apotex would not consent to the dismissal of all claims and counterclaims pending in Florida. You also confirmed that Apotex would not stay any aspect of the second-filed Florida action pending the resolution of any motions that either party might bring.

**sanofi-aventis's Dismissal of Their Claims Pending In Delaware:** I informed you that sanofi-aventis would not consent to your request to dismiss the claims pending against Apotex in Delaware.



KIRKLAND & ELLIS LLP

Steven E. Feldman, Esq.  
January 7, 2008  
Page 2

**Apotex's Motion to Transfer** You confirmed that Apotex intends to file a motion to transfer the first-filed Delaware action to the Southern District of Florida because the Southern District of Florida is a more convenient forum. You explained that Florida is a more convenient venue because Apotex Corp. is headquartered in Florida and, while you could not identify any, you are certain there are potential witnesses/deponents who reside in Florida. You also explained that at this time you were unaware as to whether any Research and Development related to Apotex's generic alfuzosin hydrochloride tablets occurred in Florida. Additionally, you stated that Apotex believes that the second-filed Florida action will be adjudicated faster than the first-filed action in Delaware because Apotex would be on its own against sanofi-aventis as opposed to in one coordinated action in Delaware involving 13 other defendants. You further stated that the Florida Courts issuance of a scheduling order, which I noted was pro forma, setting trial for May 2008 supports the conclusion that the action in Florida would proceed faster than the first-filed Delaware action. At this time, you do not know when Apotex will bring this motion. You also noted that Apotex would not agree to stay the Florida action pending resolution of Apotex's Motion to Transfer. I confirmed that sanofi-aventis would oppose Apotex's motion.

**sanofi-aventis's Motion to Transfer and Stay:** You confirmed that Apotex would oppose any motion to transfer the second-filed Florida action to Delaware that sanofi-aventis might bring.

**The '940 Patent:** I notified you that sanofi-aventis does not believe the '940 patent is in dispute against Apotex. You stated that based upon the recent *Forest Labs.* decision you disagreed. However, I informed you that I was unaware of any such decision and you identified no such decision.

Sincerely,



William T. Vuk

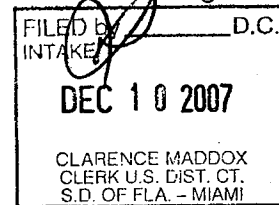
cc (via email):  
Jack Blumenfeld, Esq.  
Stephen J. Bronis, Esq.  
Richard L. Horwitz, Esq.  
Edward A. Moss, Esq.  
Alfred J. Saikali, Esq.



# **EXHIBIT M**



UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA



Case No. 07-61800

SANOFI-AVENTIS and  
SANOFI-AVENTIS U.S. LLC,  
Plaintiffs,

**CIV-MORENO**

vs.

MAGISTRATE JUDGE  
SIMONTON

APOTEX INC. and  
APOTEX CORP.,

Defendants. /

**COMPLAINT**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Apotex Inc. and Apotex Corp., hereby allege as follows:

**Parties**

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.
2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned



subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

#### **Nature of the Action**

5. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

#### **Jurisdiction and Venue**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff sanofi-aventis U.S., which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.



8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

9. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Inc. is a Florida corporation.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

#### **The '491 Patent**

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

#### **Acts Giving Rise to this Action**

##### **Infringement of the '491 Patent by Defendants**

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a



proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j)(2)(A)(vii)(IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.



18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

19. Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007, Civil Action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

**Prayer for Relief**

**WHEREFORE**, Plaintiffs pray for judgment as follows:

- A. That Defendants have infringed the '491 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Apotex Inc.'s ANDA identified in this Complaint shall not be earlier than the expiration date of the '491 patent, including any extensions;
- C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently



enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 patent, including any extensions;

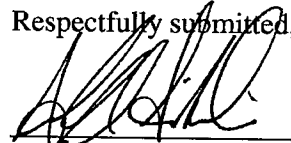
D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated this 10th day of December, 2007.  
Miami, Florida

Respectfully submitted,



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Attorney for Plaintiffs sanofi-aventis and  
sanofi-aventis U.S. LLC



# **EXHIBIT N**



**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
MIAMI DIVISION**

**Case No. 07-61800-CIV-MORENO/SIMONTON**

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SANOFI-AVENTIS and  
SANOFI-AVENTIS U.S. LLC,  
Plaintiffs,

vs.

APOTEX INC. and  
APOTEX CORP.,  
Defendants.

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**PLAINTIFFS' MOTION TO TRANSFER OR STAY  
AND SUPPORTING MEMORANDUM OF LAW**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully move the Court to transfer this action to the District of Delaware where an identical, parallel, first-filed action is currently pending. Defendants Apotex Corp. and Apotex Inc. do not contest personal jurisdiction in Delaware and admit that venue in that forum is proper. Plaintiffs' choice of forum, the first-filed rule, and the interests of justice and convenience to the parties and witnesses favor transfer of this action to Delaware where it will proceed before the same Judge and Magistrate Judge as two related actions involving 13 other defendants and the parallel action against Apotex Corp. and Apotex Inc. Alternatively, Plaintiffs respectfully move this Court to stay the present action pending the disposition of any transfer issues raised by Defendants in the first-filed forum.

Counsel for Plaintiffs certify that pursuant to Local Rule 7.1.A.3(a) it has met and conferred with counsel for Defendants in an effort to resolve the issues raised by Plaintiffs' Motion to Transfer or Stay. The parties were unable to resolve those issues.



WHEREFORE, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully requests that the Court enter an Order granting Plaintiffs' Motion to Transfer or Stay.

### **MEMORANDUM OF LAW**

This is an action brought under 35 U.S.C. § 101 *et seq.* and the Hatch-Waxman Act for the infringement of a patent covering the drug Uroxatral® by the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this memorandum in support of their motion to transfer this action to the District of Delaware where an identical, parallel, first-filed action and two related cases against 13 other defendants are currently pending. Alternatively, Plaintiffs request that the Court stay this action pending the resolution of any venue issues raised in the Delaware action by Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex").

The District of Delaware is Plaintiffs' forum of choice and the first-filed forum. This is true not only for the parallel proceeding against Apotex, but also for sanofi-aventis's claims against 13 other defendants. Plaintiffs would not have even filed this action if Apotex had timely confirmed what it has now admitted in its pleadings and in its representations to Plaintiffs — that it does not contest personal jurisdiction in Delaware and that venue is appropriate in that forum.

But rather than proceeding in Delaware where actions are currently pending against all accused infringers, Apotex seeks to game the system and engage in forum-shopping by arguing that the Southern District of Florida is more convenient and will adjudicate the parties' claims more quickly. There is scant support for either of these assertions as the majority of Apotex's documents and witnesses are likely located in Canada where it develops its generic products, and the issues involved in this patent litigation are sufficiently complex, and potential discovery so far-reaching, that they will likely take a considerable time to adjudicate regardless of the forum



in which they proceed. If Apotex's attempt to make an end-run around sanofi-aventis's choice of forum is successful, the result will be contrary to the interests of justice, leading to a waste of time and resources on duplicative discovery and other pretrial proceedings, potentially inconsistent rulings on issues that impact the certainty of patent rights, as well as great inconvenience to the parties and witnesses which will have to proceed in two separate districts. Apotex's tactics will not only impact the parties in this case, but also the 13 additional defendants in Delaware where sanofi-aventis's other patent infringement actions will proceed regardless of what happens in this jurisdiction. Consequently, the Court should follow the time-honored rule of allowing actions to proceed in the first-filed forum and transfer this case to Delaware so that all claims for patent infringement may proceed in the same court and before the same Judge and Magistrate Judge in a coordinated manner.

Alternatively, if the Court does not transfer at this time, Plaintiffs respectfully request that it stay the present action and defer to the first-filed District of Delaware on the issue of venue while the parties continue to litigate their claims and defenses in that forum.

## **BACKGROUND**

### **I. The Parties**

Plaintiff sanofi-aventis is one of the world's leading innovators in the research, development and marketing of drugs and vaccines. It is a French corporation with places of business throughout the world, including its principal place of business in Paris, France. Plaintiff sanofi-aventis U.S. LLC is sanofi-aventis's United States affiliate. It is a Delaware Limited Liability Company with its North American headquarters in the state of New Jersey.

Defendant Apotex Inc. is a Canadian Company, with a place of business in Toronto, Ontario, Canada. Defendant Apotex Corp. is a Delaware Corporation, and has places of business in a number of states, including Florida, New York and Indiana. Apotex Inc. and Apotex Corp.



sell generic drugs throughout the United States, including Delaware; according to Apotex Inc.'s website, "worldwide sales of the Apotex Group of companies exceed \$1 billion (Canadian \$) per year." Ex. 1, The Apotex Group Corporate Info.<sup>1</sup>

## **II. Sanofi-aventis's Patents And Innovator Drug**

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 (issued April 28, 1987) ("the '491 patent"), titled "Alfuzosine Compositions and Use." It is also a current assignee of United States Patent No. 6,149,940 (issued November 21, 2000) ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."<sup>2</sup> Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, the innovator drug for which Plaintiff sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287.

## **III. Infringement Of Sanofi-Aventis's Patents By The ANDA Filers**

In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), including ANDA 79-013 filed by Apotex Inc. with the participation and/or contribution of Apotex Corp. Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed generic product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the ANDA filers included "paragraph IV certifications," alleging that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale

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<sup>1</sup> True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of William T. Vuk in Support of Plaintiffs' Motion to Transfer or Stay.

<sup>2</sup> Non-party Jagotec AG is also a current assignee of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent.



of the proposed generic products. Sanofi-aventis received notification of the ANDAs and paragraph IV certifications in letters dated between August 14, 2007 and October 25, 2007, including notification of Apotex's ANDA and '940 patent paragraph IV certification by letter dated August 14, 2007 and notification that Apotex amended its ANDA to include a '491 patent paragraph IV certification by letter dated October 25, 2007. Ex. 2, 08/14/07 B. Sherman ltr to Plaintiffs and Jagotec AG; Ex. 3, 10/25/07 B. Sherman ltr to Plaintiffs and Jagotec AG.

The submission of these ANDAs and paragraph IV certifications permitted sanofi-aventis to sue for infringement of the '491 patent and/or the '940 patent. *See* 35 U.S.C. § 271(e)(2)(A). To litigate this infringement under the protections provided by the Hatch-Waxman Act, which affords a 30-month stay of generic approval while a patent litigation is pending, sanofi-aventis was required to file an action against each submitting party or parties within forty-five days of receiving notice of their respective paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iii).

#### **IV. Commencement Of The First-Filed District Of Delaware Actions**

##### **A. Plaintiffs Initially Sued 13 Defendants For Infringement of the '491 and/or '940 Patents In the District of Delaware**

After receiving notice of the ANDAs and paragraph IV certifications, sanofi-aventis evaluated various personal jurisdiction issues and determined that the most logical venue for litigating its claims against all 15 potential defendants, including Apotex, was the District of Delaware. In light of this fact and the judicial economy and efficiency of having the same court try each of sanofi-aventis's claims against all defendants, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in the United States District Court for the District of Delaware against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.<sup>3</sup>

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<sup>3</sup> In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940



See Ex. 4, Delaware Complaint No. 07-572; Ex. 5, Delaware Complaint No. 07-574.

**B. Plaintiffs Sued Apotex For Infringement Of The '491 Patent In The District Of Delaware Shortly Thereafter**

At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product. Ex. 6, 10/01/07 W. Vuk ltr to B. Tao. Sanofi-aventis then received a second paragraph IV certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. In response, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent. Ex. 7, Apotex Delaware Complaint. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge.

**C. Apotex Agreed Not To Contest Jurisdiction In The District Of Delaware Only After The Expiration Of Plaintiffs' 45-Day Window To Bring Suit**

Despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware,<sup>4</sup> Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. See Ex. 9, 12/06/07 W. Vuk ltr to B. Sherman. It was only after that period ran that Apotex represented

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patent alone against four additional defendants.

<sup>4</sup> On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. Ex. 8, Answer in *Allergan, Inc. v. Apotex Inc. et al*, Civ. No. 07-278-GMS at 2-3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al*, No. Civ. 07-204-SLR at 3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al*, No. Civ. 06-164-SLR at 3-4; Answer in *Merck & Co., Inc. v. Apotex Inc.*, No. Civ. 06-230-GMS at 2. In fact, Apotex has also availed itself of the Delaware court as a plaintiff. Ex. 8, Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4.



that it would not contest jurisdiction in Delaware. Ex. 10, 12/11/07 M. Noreika email to S.

Rollo; Ex. 11, 12/31/07 M. Noreika ltr to S. Rollo. On January 2, 2008, Apotex answered the complaint in Delaware and conceded that jurisdiction and venue were proper in Delaware:

- "Apotex Corp. admits that [the Delaware] Court has personal jurisdiction over it in this District for the purposes of this action." *See* Ex. 12, Apotex Delaware Answer And Counterclaims ¶ 7.
- "For purposes of this action, Apotex Inc. does not contest the [Delaware] Court's jurisdiction over it . . . ." *Id.* ¶ 8;
- "Apotex Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action . . . ." *Id.* ¶ 10.

Despite these clear admissions to the Delaware court as to the appropriateness of jurisdiction and venue, Apotex has indicated that it will move to transfer the first-filed Delaware action to the Southern District of Florida because that is "a more convenient venue" and "will proceed more quickly to resolution." *See* Ex. 12 ¶ 10; Ex. 13, 01/07/08 S. Feldman ltr to W. Vuk; Ex. 14, 01/07/08 W. Vuk ltr to S. Feldman.

All three first-filed Delaware actions are designated as related cases and all are proceeding before the same Judge and the same Magistrate Judge. As of January 7, 2008, all 15 defendants, including Apotex, have filed their answers and counterclaims and sanofi-aventis has filed all of its replies. The parties now await an order setting the Rule 26(f) scheduling conference. *See* Ex. 15, Delaware Docket Sheets.<sup>5</sup>

#### **V. Plaintiffs Brought The Present Action To Protect Their Rights Under The Hatch-Waxman Regime In Response To Apotex's Failure To Confirm That It Would Not Contest Jurisdiction In Delaware**

Apotex's refusal to consent to jurisdiction in Delaware within the 45-day window to bring

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<sup>5</sup> One additional protective suit is currently pending against Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. Plaintiffs have not served the complaint in that action and expect that their claims against the Aurobindo defendants will proceed in the District of Delaware where jurisdiction and venue are proper with respect to both parties.



suit placed sanofi-aventis in a significant dilemma. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at \*8 (N.D. Ill. Mar. 28, 2006) (citing 21 U.S.C. § 355 (j)(5)(B)(iii)). Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in Delaware and with respect to Apotex by its December 6, 2007 complaint in Delaware. But it is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See PDL BioPharma, Inc. v. Sun Pharm. Inds., Ltd.*, No. 07-11709, 2007 WL 2261386, at \*2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at \*8.

Although sanofi-aventis believed that the District of Delaware could properly exercise personal jurisdiction over Apotex, this is the only district in which sanofi-aventis knew Apotex would not contest personal jurisdiction based on prior litigation conduct and representations made in Apotex's certification letters. Given the uncertain consequences surrounding the unlikely, but possible dismissal of the Delaware action, sanofi-aventis had no choice but to bring this second-filed action within the 45-day window on December 10, 2007.<sup>6</sup> Ex. 16, Florida

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<sup>6</sup> The consequences of losing the protections of the Hatch-Waxman Act are significant to the parties and the courts. Under the Act, approval of the proposed generic product is stayed by the FDA for 30 months and the action can be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation."); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and patentee plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.



Complaint. As discussed above, Apotex subsequently agreed not to contest jurisdiction in Delaware, but would not confirm that agreement in writing so that sanofi-aventis could voluntarily dismiss the Florida complaint.

It is now clear that this tactic was an attempt to make an end rule around Plaintiffs' choice of forum. Apotex filed its Answer and Counterclaims in this action on December 28, 2007, one business day before answering the first-filed Delaware action, in a thinly-veiled attempt to manufacture an argument that this action is at a more advanced state than the first-filed Delaware actions.<sup>7</sup> *See* Ex. 17, Florida Answer And Counterclaims; Ex. 18, Florida Amended Answer And Counterclaims. It appears that Apotex's strategy was to ignore sanofi-aventis's inquiry as to whether it would contest jurisdiction in Delaware, in an effort to force sanofi-aventis to file a protective action in Apotex's forum of choice. Apotex now seeks to buttress its argument that this forum is "more convenient" with the "fact" that this action has progressed farther than the Delaware actions because it filed its answer in Florida one business day before answering in Delaware. As discussed below, similar attempts by ANDA filers to game the system and to secure the forum of their choice at the expense of the plaintiff have failed.

## ARGUMENT

### **I. All Relevant Factors Favor Transfer To Delaware Where Identical Claims And Counterclaims Are Pending With Related Claims Against 13 Other Defendants**

Where venue is proper, a federal court, "[f]or the convenience of parties and witnesses, in the interest of justice, may transfer any civil action to any other district or division where it might have been brought." 28 U.S.C. § 1404(a). Thus, the question of whether to transfer is a two-part inquiry. First, the transferee forum must be one in which the action could originally have been

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<sup>7</sup> In its Florida answer, Apotex "den[ies] that Apotex Inc. is subject to personal jurisdiction in the Delaware action . . . ." Ex. 17 ¶ 19. Apotex then contradicted that denial in its Delaware Answer, stating that it does not contest the Delaware court's personal jurisdiction over Apotex Inc. Ex. 12 ¶ 8; *see also* Ex. 10; Ex. 11.



brought. Second, the Court must balance factors such as the plaintiff's choice of forum, the interests of justice, and the convenience of the parties and witnesses in deciding whether on the whole they favor transfer. *Manuel v. Convergys Corp.*, 430 F.3d 1132, 1135 n.1 (11th Cir. 2005).

There is no dispute that this Court has the power to transfer this action to the District of Delaware as, unlike the circumstances of many motions to transfer, sanofi-aventis and Apotex agree that jurisdiction and venue are proper in Delaware. The Court should exercise its power and transfer this action to the first-filed forum for adjudication with the parties' identical claims pending in that court along with two related patent infringement litigations involving the same patents-in-suit and reference drug—actions that will proceed regardless of what happens in this forum. First, Delaware is both Plaintiffs' forum of choice and the first-filed forum, two factors that weigh heavily in favor of transfer. Second, transfer would avoid the duplicative efforts and costs of two separate courts conducting extensive pretrial activities and prevent potentially inconsistent rulings on critical issues such as claim construction and summary judgment. Finally, although Apotex claims that it would be more convenient for it to proceed in this forum, that convenience is minimal as most of its relevant witnesses and documents are likely located in Canada where it develops generic products. Additionally, it is likely that this action will take a significant amount of time to adjudicate regardless of where it proceeds in light of the complex nature of the case and the expected scope of discovery. Any minimal added burden of litigating in Delaware, where Apotex has recently litigated several other ANDA actions without moving to transfer, is heavily outweighed by the interests of judicial economy and certainty of patent rights as well as the inconvenience the parties would experience by litigating the same issues in two separate judicial districts. *See Abbott*, 2006 WL 850916, at \*8 (finding an ANDA filer's convenience argument less persuasive when it had litigated multiple ANDA cases in the forum without complaint).



**A. Both the Plaintiffs' Choice of Forum and the First-Filed Rule Favor Transfer**

Plaintiff's choice of forum weighs in favor of a request to transfer and should not be disturbed unless clearly outweighed by other considerations. *Cf. Robinson v. Giarmarco & Bill, P.C.*, 74 F.3d 253, 260 (11th Cir. 1996) (refusing to transfer outside of plaintiffs' forum where such a transfer would merely shift the burdens on the parties). Here, sanofi-aventis chose the District of Delaware because it was the district where Plaintiffs could bring each of the ANDA filers and related defendants under the jurisdiction of the court so that all claims and counterclaims concerning Uroxatral® and the listed patents could be adjudicated in a single forum. Plaintiffs were only forced to bring this second-filed action because Apotex refused to confirm that it would not contest jurisdiction in Delaware within the 45-day window Plaintiffs had to bring suit under the Hatch-Waxman Act. *See, e.g.*, Ex. 9. As discussed above, the law remains unclear as to whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act, namely the 30-month stay of approval of the proposed generic product, if its action, properly brought within the 45-day window, is later dismissed for lack of personal jurisdiction. *See Abbott*, 2006 WL 850916, at \*8; *PDL*, 2007 WL 2261386, at \*2. Now that Apotex has acknowledged that it does not contest personal jurisdiction in Delaware, the Court should transfer this action to Plaintiffs' forum of choice. *See* Ex. 10; Ex. 11; Ex. 12 ¶¶ 7-10.

Transfer under this set of facts would also comport with the 11th Circuit's "first-filed" rule. Under that standard, if two actions involving the same parties and identical issues are pending in different districts, the first-filed action should typically be given priority and be allowed to proceed in favor of the later action. *See Manuel*, 430 F.3d at 1135-38 ("[W]here two actions involving overlapping issues and parties are pending in two federal courts, there is a strong presumption across the federal circuits that favors the forum of the first-filed suit under the first-filed rule."); *Philibert v. Ethicon, Inc.*, No. 04-81101-CIV, 2005 WL 525330, at \*1 (S.D.



Fla. Jan. 14, 2005). Contrary to Apotex's unsupported assertions, this rule applies even where plaintiff files both actions, a measure that courts have recognized as necessary under the Hatch-Waxman Act. Ex. 14; *PDL*, 2007 WL 2261386, at \*2; *see also Cordis Corp. v. Siemens-Pacesetter, Inc.*, 682 F. Supp. 1200, 1202-03 (S.D. Fla. 1987) (rejecting defendants' assertion that a plaintiff must show a change of circumstances when moving under § 1404 and ordering transfer to the first filed forum where four related litigations involving these and other defendants were already pending).<sup>8</sup>

Sanofi-aventis filed the Delaware action against Apotex on December 6, 2007. The Florida action was filed on December 10, 2007, but never served. Both the Delaware and the Florida actions raise the same issues—namely, whether Apotex's proposed generic version of Uroxatral® infringes any valid and enforceable claim of the '491 patent, and to the extent Apotex's counterclaims are not dismissed, whether that product infringes any valid and enforceable claim of the '940 patent. Consequently, the Court should transfer this action under the first-filed rule. *Philibert*, 2005 WL 525330 at \*2 (transferring to the first-filed forum where identical claims were pending to serve the interests of justice); *Tiber Labs., LLC v. Cypress Pharm., Inc.*, No. 2:07-CV-0014-RWS, 2007 WL 3216625, at \*2-3 (N.D. Ga. May 11, 2007).

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<sup>8</sup> The first-filed rule is measured by which action was filed first, not by when counterclaims are first filed. Consequently, Delaware is the first-filed forum in this case, even though Apotex's counterclaims with respect to the '940 patent were filed in this District one business day before filing them in Delaware. *See Kimberly-Clark Corp. v. McNeil-PPC, Inc.*, 260 F. Supp. 2d 738, 740-41 (E.D. Wis. 2003) (rejecting a similar argument concerning declaratory judgment counterclaims asserted in the second-filed action concerning patents not initially at issue in the first-filed action because "[t]he issue, however, is not which of the claims was filed first, but rather which action was filed first."); *Versus Tech., Inc. v. Hillenbrand Indus., Inc.*, No. 1:04-CV-168, 2004 WL 3457629, at \*6-7 (W.D. Mich. Nov. 23, 2004); *cf. Holmes Group, Inc. v. Vornado Air Circulation Sys. Inc.*, 535 U.S. 826, 831-32 (2002) (holding that counterclaims cannot serve as the basis for "arising under" jurisdiction under the well-pleaded complaint rule).



**B. The Interests of Justice Can Only Be Served By Transfer To The Forum Where All Others Claims Concerning The Patents Are Pending**

As the Federal Circuit has held, "consideration of the interest of justice, 'may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result.'" *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1565 (Fed. Cir. 1997).

For example, in *Alere Medical, Inc. v. Health Hero Network, Inc.*, a first-filed action was brought in Illinois for infringement of plaintiff's patent. No. C- 07-05054 CRB, 2007 WL 4351019, at \*1 (N.D. Cal. Dec. 12, 2007). The accused infringer subsequently filed a separate declaratory judgment action in California concerning seven other patents owned by the patentee, but not at issue in the first-filed action. The second-filed court granted the accused infringer's motion to transfer its declaratory judgment action to the first-filed forum because, *inter alia*, the related actions "share[] common technology and products, common parties, and overlapping issues of infringement and validity. Having all the patents before a single judge will obviate the need for duplicative tutorials and evidence, and will facilitate a global settlement." *Id.* Rejecting the patentee's argument that transfer would be inconvenient in light of the location of relevant witnesses, parties, and documents, the court stated that "the pertinent question is not simply whether *this* action would be more conveniently litigated in Illinois than California, but whether it would be more convenient to litigate the California and Illinois actions separately or in a coordinated fashion." *Id.* at \*2; *Cordis Corp.*, 682 F. Supp. at 1202 (S.D. Fla. 1987).

Likewise, in *Tingley Systems, Inc. v. Bay State HMO Management, Inc.*, the second-filed court granted defendant's motion to transfer to the first-filed forum even though defendant had not proven that its witnesses would be more inconvenienced than plaintiff's witnesses without a transfer. 833 F. Supp. 882, 886 (M.D. Fla. 1993). What defendant had established, however, was that "all parties and witnesses would be greatly burdened if all were required to travel



between two forums because the two related cases in which they were all involved were being tried in different states." *Id.* By transferring the second-filed action in the interest of justice, the Court held that all the parties would benefit because:

The two actions should be consolidated before one judge thereby promoting judicial efficiency, pretrial discovery could be conducted in a more orderly manner, witnesses could be saved the time and expense of appearing at trial in more than one court, duplicative litigation involving the filing of records in both courts could be avoided eliminating unnecessary expense and the possibility of inconsistent results could be avoided."

*Id.* at 888 (internal quotations omitted).

The facts supporting transfer are even more compelling here where sanofi-aventis has multiple suits pending in the District of Delaware that share the same claims and counterclaims concerning the '491 and '940 patents. In addition to the parallel action against Apotex, there are two other cases concerning infringement of the same patents by eight additional ANDAs referencing Uroxatral®, which will proceed regardless of what happens in this forum. Each of these actions has been assigned to the same Judge and Magistrate Judge. All answers and replies have been filed and the parties now await an initial scheduling order from the court. Plaintiffs expect that the Delaware court will coordinate pretrial activities in all three pending cases, and may consolidate all three actions for pretrial proceedings, in order to avoid duplicative discovery efforts and improve the efficiency of its docket.

By transferring this action for coordination with the Delaware cases, the Court will avoid duplicating pretrial activities, thus preserving judicial resources and reducing costs for the parties. For example, as the issues with respect to Plaintiffs' activities concerning the reference product Uroxatral® and the patents-in-suit are identical, transfer will avoid multiple depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which the ANDA filers may seek discovery.



Likewise, transfer will avoid duplicative discovery disputes concerning these issues being adjudicated by separate courts. Moreover, transfer to Delaware will obviate the need for multiple courts to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products.

Finally, transfer will prevent potentially inconsistent rulings on critical issues such as the validity and enforceability of the asserted claims, and, to the extent the ANDA filers allege similar defenses, whether the proposed generic products infringe those claims. This factor is especially important with respect to the specialized *Markman* hearing courts must hold to construe the meaning of asserted claim terms as a matter of law, where inconsistent rulings could result in identical claim terms having different meaning for different defendants. *See Cordis*, 682 F. Supp. at 1202; *cf. MRL, LLC v. U.S. Robotics Corp.*, No. 02 C 2898, 2003 WL 685504, at \*1-2 (N.D. Ill. Feb. 26, 2003) (denying motion to stay under an exception to the first-filed rule in favor of the second action where patentee's claims for infringement were pending before all accused infringers and would proceed regardless of whether the stay was granted); *Eason v. Linden Avionics, Inc.*, 706 F. Supp. 311, 330 (D.N.J. 1989) ("[L]itigation of related claims in the same tribunal is strongly favored because 'it facilitates efficient, economical and expeditious pretrial proceedings and discovery and avoids [duplicative] litigation and inconsistent results.'").

### **C. Apotex's Unsupported Convenience And Congestion Arguments Are Substantially Outweighed By The Other Relevant Factors**

Apotex argues that it would be more convenient for the witnesses and the parties to proceed in the Southern District of Florida, because Apotex Corp. is based in this District. Ex. 12 ¶ 10; Ex. 18 ¶ 19. As discussed above, Apotex is part of a multinational, billion dollar group of companies and has proceeded in Delaware in several other ANDA litigations without moving to transfer. In this case, as in the *Alere* and *Tingley* cases discussed above, any marginal convenience to Apotex of proceeding in Florida is vastly outweighed by the courts' and the



parties' interests in avoiding duplicative pretrial activities, in preventing potentially inconsistent rulings, and the inconvenience to the parties of having to proceed in two separate jurisdictions.

Apotex recently tried unsuccessfully to transfer an ANDA infringement action from the Southern District of Indiana to this forum even though there were no related actions pending in Indiana, let alone claims against 13 other defendants as in the case at bar. *See Alcon Mfg., Ltd. v. Apotex Inc.*, No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026 (S.D. Ind. Mar. 14, 2007). In *Alcon*, Apotex argued that (1) this forum was more convenient to Apotex and its witnesses and no less convenient for the plaintiff and (2) the interests of justice favored this forum because it had an interest in deciding local controversies and could conduct a more speedy trial.

The *Alcon* court rejected both of Apotex's arguments. First, the court found that Florida was not a more convenient forum because the parties were spread throughout the United States and internationally; thus, any financial burden of proceeding in the first-filed forum was insufficient to overcome the deference in plaintiff's choice of forum, even though it was not the plaintiff's home district. *Alcon*, 2007 WL 854026, at \*2-3. Second, Apotex failed to show that transfer to Florida would be more convenient to the witnesses, as Apotex's development of its proposed generic product and preparation of the ANDA took place in Canada and plaintiffs' research and development of the patented product took place in Texas and Japan; thus, both parties' witnesses would have to travel to either the first- or second-filed forum, with the only apparent exception being the president of Apotex USA. *Id.*; *see also Abbott*, 2006 WL 850916, at \*7 ("In a case where all of the witnesses of the [generic] defendant will be its employees, however, the location is not as important a factor as it would be if the witnesses were not under the control of the defendant."). Finally, the court rejected Apotex's interest of justice arguments as the suit was likely to affect consumers nationwide, not just in Florida, and because the case involved complex issues concerning patent infringement, it would likely take several years to



adjudicate, regardless of the venue. *Alcon*, 2007 WL 854026, at \*4.

This case falls squarely within the *Alcon* court's rationale. Sanofi-aventis's witnesses and documents are likely to be found in Europe, New Jersey, and Pennsylvania, not Florida. As in *Alcon*, Apotex Inc., the Canadian corporation, is the holder of the ANDA, and it is likely that Canada is the situs of events such as preparation of that ANDA and its underlying research and development as well as the documents concerning and the witnesses with knowledge of those issues. Likewise, Apotex can make no showing this is a local dispute over which Florida has any specialized interest because Uroxatral® is sold throughout the country and Plaintiffs expect that Apotex will seek to market its products well beyond the borders of this forum as it has with its other generic products developed and manufactured abroad.

Apotex has indicated that the interest of a speedy trial necessitates proceeding in this Court. Ex. 13, Ex. 14. That argument failed in *Alcon* and should fail here as well. This is a complex litigation that will require the resolution of a variety of patent-specific issues, such as claim construction, infringement, and validity that will take a significant amount of time to adjudicate. Plaintiffs expect that Apotex will seek discovery on a wide-range of issues concerning the development of sanofi-aventis's inventions, patent prosecution, alleged prior art, and various marketing and regulatory activities. Many of the hundreds of thousands of potentially relevant documents are decades old and are located overseas where they must be reviewed in compliance with the European Union and member-state privacy directives prior to transport to the United States. Considering the number of inventors and other potentially relevant witnesses, including third parties, Plaintiffs expect the parties to conduct a large number of depositions, some of which may require Apotex to seek relief under the Hague Convention. Consequently, sanofi-aventis will ask Apotex to consent, or otherwise move the Court, to place this action on a Complex Track under Local Rule 16.1.A to ensure that the parties conduct



discovery in a fair and efficacious manner and fully develop their claims and defenses prior to trial.

And here of course, there is the additional factor that was not present in *Alcon*: that there are actions pending against 13 other defendants in the first-filed forum that must proceed regardless of where the present case is adjudicated.<sup>9</sup>

## **II. Alternatively, This Court Should Exercise Its Discretion To Stay This Action Pending The District Of Delaware's Adjudication Of Any Transfer Issues**

If the Court does not transfer, sanofi-aventis respectfully requests that it stay the present action pending resolution of any transfer issues raised by Apotex in the first-filed Delaware action. It is well-settled that district courts have discretion to stay an action to give priority to first-filed parallel proceedings in another district. *See, e.g., Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 183-4 (1952); *Landis v. N. Am. Co.*, 299 U.S. 248 (1936); *Perkins v. Am. Nat. Ins. Co.*, 446 F. Supp. 2d 1350, 1353-54 (M.D. Ga. 2006). This power to stay actions is in the interest of "[w]ise judicial administration, giving regard to conservation of judicial resources and comprehensive disposition of litigation . . . ." *Kerotest*, 342 U.S. at 183; *Landis*, 299 U.S. at 254; *Lisa v. Mayorga*, 232 F. Supp. 2d 1325, 1326 (S.D. Fla. 2002). In deciding whether to order a stay, a district court should weigh the factors of judicial economy and balance the interests of the parties and the Court. *Id.*

The court in *PDL Biopharma, Inc. v. Sun Pharmaceutical Ind., Ltd.* was faced with a similar situation in which the patentee and NDA holder PDL moved to stay a second-filed so-called "protective action" based on the "first-filed" rule. ANDA filer and defendant Sun opposed

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<sup>9</sup> For the forgoing reasons, Plaintiffs expect that Apotex will likely fail in any motion to transfer the Delaware action to this forum. *See, e.g., Auto. Techs. Int'l, Inc. v. Amer. Honda Motor Co., Inc.*, No. 06-187 GMS, 2006 WL 3783477, at \*2-3 (D. Del. Dec. 21, 2006) (denying motion to transfer where, *inter alia*, plaintiff had a rational and legitimate reason to sue defendants in the forum and noting that "a flight to Delaware is not an onerous task warranting transfer.").



the motion arguing that the "first-filed" rule should not apply because PDL was allegedly motivated by bad faith or forum shopping. Concerned that going forward with two identical actions simultaneously would waste scarce judicial resources and present the distinct possibility of conflicting rulings or judgments, the court overseeing the second-filed action held that application of the first-filed rule was appropriate and granted the stay. *PDL*, 2007 WL 2261386, at \*2. The court rejected Sun's complaints of bad faith and forum shopping stating that:

Plaintiff filed the duplicative actions only because of the extraordinary time limit placed on the filing of suits under the Hatch-Waxman Act. Plaintiff correctly believed that Defendant would challenge personal jurisdiction in Plaintiff's preferred forum and concluded that, should a court in Plaintiff's preferred forum of the District of New Jersey find that jurisdiction was not appropriate there, the timing of the ruling could preclude Plaintiff from filing *any* action under the Act. These circumstances do not demonstrate bad faith or forum shopping on the part of Plaintiff. Furthermore, given the strict deadline and the potentially harsh outcome should Plaintiff's preferred forum dismiss the cause of action after the deadline, a consideration of the 'extraordinary circumstances' of the case weighs in favor of the stay.

*Id.* "[G]iven the unusual nature of ANDA claims and absent any guidance," the court found that plaintiff had satisfied its burden for a stay." *Id.*; see Ex. 19, *Abbott Labs. v. Andrx Corp.*, Case 00-6520-CV-S, Transcript of Scheduling Conference (S.D. Fla. July 10, 2000) at 12-13 (staying second-filed action while jurisdictional issues were pending before the first-filed court).

The facts in the present case are identical in all relevant respects to those in *PDL*. Sanofi-aventis was forced by Apotex's temporary refusal to consent to jurisdiction in Delaware until after the 45-day period for bringing suit—and the lack of guidance in the statute and case law regarding the effect of the possible dismissal of a suit for lack of personal jurisdiction on a patentee's Hatch-Waxman rights—to file a "protective action" in this District. Sanofi-aventis had a reasonable basis for concluding that Apotex is subject to jurisdiction in the District of Delaware, including Apotex's prior admissions in other ANDA litigations, which has been confirmed by Apotex's subsequent representations to the Delaware court that it will not challenge



jurisdiction. *See* Ex. 12. Apotex can hardly argue that sanofi-aventis's filing of parallel actions, or this motion, are motivated by bad faith or forum shopping. *See PDL*, 2007 WL 2261386, at \*2; *see also Abbott*, 2006 WL 850916, at \*8.

As in *PDL*, balancing the interests of the parties favors a stay of this action. Requiring the parties to litigate the same issues in this action in parallel to the first-filed Delaware actions is likely to lead to significant duplication of effort and expense, as discussed above with respect to transfer. There is no prejudice to weigh against these interests as the parties will continue to litigate their claims and defenses in the District of Delaware. Moreover, in the unlikely event that Apotex successfully moves the Delaware court to transfer the first-filed action here, the Court can immediately lift the stay and proceed in this case.

### CONCLUSION

For all the foregoing reasons sanofi-aventis requests that the Court transfer this action to the District of Delaware. In the alternative, sanofi-aventis requests that the Courts stay this action until the District of Delaware adjudicates any motion to transfer brought by Apotex.

Dated: January 8, 2008

Respectfully submitted,

**SHOOK, HARDY & BACON L.L.P.**

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*Attorneys for Plaintiffs*



**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on January 8, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

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*Attorneys for Plaintiffs*



**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court  
Southern District of Florida  
(Miami Division)**

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Apotex, Inc.*  
201 South Biscayne Blvd., Suite 900  
Miami, FL 33131

*VIA CM/ECF*



UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
MIAMI DIVISION

Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and  
SANOFI-AVENTIS U.S. LLC,  
Plaintiffs,

vs.

APOTEX INC. and  
APOTEX CORP.,

Defendants.

**[PROPOSED] ORDER GRANTING  
PLAINTIFFS' MOTION TO TRANSFER OR STAY**

THIS CAUSE is before the Court on Plaintiffs' Motion to Transfer or Stay, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that:

- ☐ The above-captioned proceeding is hereby transferred to the United States District Court for the District of Delaware.

☐ The above-caption proceeding is hereby stayed until the District of Delaware adjudicates any motion to transfer brought by Defendants.
- The Parties are hereby authorized to take action consistent with this Court's ruling.

DONE AND ORDERED in Chambers at \_\_\_\_\_, \_\_\_\_\_ County, Florida, this \_\_\_\_\_ day of January, 2008.

\_\_\_\_\_  
Honorable Federico A. Moreno  
United States District Court Judge



# **EXHIBIT O**



UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and  
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and  
APOTEX CORP.,

Defendants.

\_\_\_\_\_/

**ANSWER OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT, AFFIRMATIVE  
DEFENSES AND COUNTERCLAIMS**

Defendants, Apotex Inc. and Apotex Corp., Answer the Complaint of Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") as follows:

**Parties**

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

**ANSWER:** Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 1 of the Complaint, and on that basis deny such averments.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.



**ANSWER:** Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 2 of the Complaint, and on that basis deny such averments.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9; that Apotex, Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings, Inc. and that Apotex, Inc. manufactures numerous drugs that are sold and used in this judicial district. Apotex, Inc. and Apotex Corp. deny that Apotex Pharmaceutical Holdings, Inc. is a wholly-owned subsidiary of Apotex Holdings, Inc. Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments in Paragraph 3 with respect to whether its products are sold and used "throughout the United States", and on that basis deny such averments.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326, but deny that Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.



**Nature of the Action**

5. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Plaintiffs' Complaint purports to bring this action for the alleged infringement of United States Patent No. 4,661,491 ("the '491 patent") and that a copy of the '491 patent appears to be attached to the Complaint as Exhibit A. Apotex, Inc. and Apotex Corp. also admits that Plaintiffs purport to bring this action based on the Patent Laws of the United States, 35 U.S.C. §1 *et seq.*

**Jurisdiction and Venue**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the subject matter of this action.

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortuous action of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff Sanofi-Aventis U.S., which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

**ANSWER:** Apotex Corp. admits that this Court has personal jurisdiction over it in this District for the purposes of this action. For purposes of this action, Apotex, Inc. does not contest the Court's personal jurisdiction over it. Apotex, Inc. and Apotex Corp. deny the averments against them to the extent they assert Apotex, Inc. and Apotex Corp. committed or aided, abetted, contributed to and/or participated in the commission of the referenced acts of patent infringement or that Plaintiff Sanofi-Aventis U.S. has been injured or otherwise harmed through



any alleged tortious acts of Defendants. As to the remaining averments, Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to their truth or falsity and on that basis deny such averments.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

**ANSWER:** For purposes of this action, Apotex, Inc. does not contest the Court's jurisdiction over it, but denies the alleged basis for personal jurisdiction asserted in this paragraph, including that Apotex Corp. is Apotex, Inc.'s "sister corporation and agent."

9. This Court has personal jurisdiction over Apotex Corp. By virtue of the fact that, *inter alia*, Apotex Inc. is a Florida corporation.

**ANSWER:** Apotex Corp. does not contest the Court's jurisdiction over it in this action, but denies that Apotex Inc. is a Florida corporation. Apotex Corp. does have its principal place of business in Florida at 2400 North Commerce Parkway, Weston, Florida 33326.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that venue is proper in this judicial district.

#### **The '491 Patent**

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.



**ANSWER:** Apotex, Inc. and Apotex Corp. admit that the '491 patent issued on April 28, 1987, but deny that this patent was duly and legally issued. Apotex, Inc. and Apotex Corp. admit that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® and that Sanofi-Aventis U.S. is listed as the Applicant for NDA No. 21-287. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of Paragraph 11 of the Complaint, and on that basis deny such averments.

**Acts Giving Rise to this Action**  
**Infringement of the '491 Patent by Defendants**

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. filed its ANDA No. 79-013 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10mg strength. Defendants admit that Apotex, Inc. seeks FDA approval to market the proposed product identified in its ANDA prior to the expiration of the '491 patent. The remaining averments of this paragraph are denied.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j) (2) (A) (vii) (IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j) (2) (A) (vii) (IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. provided Plaintiffs with notice of its ANDA No. 79-013, that such notice satisfied all statutory and regulatory



requirements and that Plaintiffs received notice on or about October 25, 2007. The remaining averments of this paragraph are denied.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j) (2) (A) (vii) (IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 14 of the Complaint.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 15 of the Complaint.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j) (2) (A) (vii) (IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 16 of the Complaint.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j) (2) (A) (vii) (IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 17 of the Complaint. Further, this allegation has no basis in fact or law and unless it is withdrawn, Defendants will seek sanctions under Rule 11 of the Federal Rules of Civil Procedure.



18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 18 of the Complaint.

19. Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007 Civil action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Plaintiffs filed an action against them in the District of Delaware. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the averments concerning Plaintiffs' intentions, knowledge or beliefs, and on that basis deny such averments. Apotex, Inc. and Apotex Corp. deny that Apotex, Inc. is subject to personal jurisdiction in the Delaware action and deny that judicial economy would be promoted by proceeding with the Delaware action as opposed to this action.

#### **GENERAL DENIAL**

Any allegation in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' Complaint, Defendants deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or any relief whatsoever.



### **AFFIRMATIVE DEFENSES**

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following affirmative defenses to the Complaint:

#### **FIRST AFFIRMATIVE DEFENSE**

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of Apotex Inc.'s ANDA No. 79-013 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '491 patent, either literally or under the doctrine of equivalents.

#### **SECOND AFFIRMATIVE DEFENSE**

The claims of the '491 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112.

#### **THIRD AFFIRMATIVE DEFENSE**

Plaintiffs have failed to state a claim on which relief can be granted. Defendants reserve their right to assert any and all additional defenses and counterclaims that discovery may reveal.

### **COUNTERCLAIMS**

Apotex Inc. and Apotex Corp., (collectively "counterplaintiffs") for their Counterclaims against Sanofi-Aventis ("Sanofi-Aventis") and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S.") (the counter-defendants will be referred to herein collectively as "Sanofi"), allege as follows:



### **The Parties**

1. Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Ontario, Canada M9L 1 T9.
2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida 33326.
3. Sanofi-Aventis U.S. has alleged that it is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
4. Sanofi-Aventis has alleged that it is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

### **Jurisdiction and Venue**

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter “Hatch-Waxman Amendments”), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter “MMA”).
6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338 (a).
7. The Court has personal jurisdiction over Sanofi because Sanofi has availed themselves to the rights and privileges of this forum by suing counterplaintiffs in this District



and because Apotex Corp. conducts substantial business in and has regular systematic contacts with this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400 (b).

**Patents-in-Suit**

9. On or about April 28, 1987, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,661,491 ("the '491 patent"), entitled "AFLUZOSINE COMPOSITIONS AND USE" to Francois Regnier.

10. Sanofi-Aventis purports to own and to have the right to enforce the '491 patent.

11. On or about November 21, 2000, the PTO issued U.S. Patent No. 6,149,940 ("the '940 patent") entitled "TABLET WITH CONTROLLED RELEASE OF AFLUZOSINE CHLORHYDRATE" to Laretta Maggi, Ubaldo Conte, Busto Arisizio, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau and Clemence Rauch-Desanti.

12. Sanofi-Aventis purports to own an interest in '940 patent and on information and belief has an exclusive license and the right to unilaterally bring and proceed with lawsuits to enforce the '940 patent in its own name.

13. Sanofi-Aventis U.S. is identified as the owner of New Drug Application No. 21-287 on Uroxatral brand alfuzosin hydrochloride extended release tablets. The '491 patent and the '940 patent are listed in the Orange Book for Uroxatral.

14. Sanofi has attempted to enforce the '940 patent against multiple other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets.

15. Apotex has submitted an abbreviated new drug application (ANDA) No. 70-013 to the FDA. Apotex Inc.'s ANDA seeks FDA approval for the commercial use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet.



16. Pursuant to 21 U.S.C. § 355(j) (2) (B) (ii) and 21 C.F.R. § 314.95, Apotex has certified to Sanofi that the '491 patent and the '940 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the new drug for which ANDA 70-013 is submitted.

17. On or about August 14, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '940 patent.

18. On or about October 15, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '491 patent.

19. On or about December 10, 2007, Sanofi sued Apotex Inc and Apotex Corp in this District alleging infringement of the '491 patent under 35 U.S.C. § 271 (e)(2)(A).

20. Counterplaintiffs have a reasonable apprehension of being sued by Sanofi for alleged infringement of the '940 patent because, *inter alia*, Apotex, Inc. has served Sanofi with its Paragraph IV certification letter asserting that the '940 patent was not infringed, Sanofi has sued more than ten other ANDA holders seeking to market alfuzosin hydrochloride extended release tablets for alleged infringement of the '940 patent, and Sanofi already has sued counterplaintiffs for infringement of the '491 patent in this court.

21. As a result of Sanofi's actions in listing of the '491 and '940 patents in the Orange Book and in suing counterplaintiffs for infringement of the '491 patent, counterplaintiffs are presently prevented from selling alfuzosin hydrochloride extended release tablets and are being



injured as a result. Counterplaintiffs seek patent certainty with respect to the '491 and '940 patents and certainty regarding the legal rights relating to Apotex, Inc.'s ANDA through a judicial declaration that the '491 and '940 patents are not infringed by the alfuzosin hydrochloride extended release tablets identified in Apotex, Inc.'s ANDA, or that the patents are invalid.

22. A real, actual, and justiciable controversy exists between counterplaintiffs and Sanofi regarding the invalidity of the '491 and '940 patents and counterplaintiffs' non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

**COUNT I**  
**(Declaration of Non-Infringement of the '491 Patent)**

23. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-22.

24. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

25. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.



**COUNT II**  
**(Declaration of Invalidity of the '491 Patent)**

26. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-25.

27. The claims of the '491 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

28. Counterplaintiffs are entitled to a declaration that the claims of the '491 patent are invalid.

**COUNT III**  
**(Declaration of Non-infringement of the '940 Patent)**

29. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-28.

30. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

31. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

**COUNT IV**  
**(Declaration of Invalidity of the '940 Patent)**

32. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-31.



33. The claims of the '940 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

34. Counterplaintiffs are entitled to a declaration that the claims of the '940 patent are invalid.

**REQUEST FOR RELIEF**

WHEREFORE, Defendants Apotex Inc. and Apotex Corp. respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Sanofi-Aventis and Sanofi-Aventis US as follows:

- (a) Declaring that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent;
- (b) Declaring that the claims of the '491 patent are invalid;
- (c) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent;
- (d) Declaring that the claims of the '940 patent are invalid;
- (e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding counterplaintiffs their attorneys' fees, costs, and expenses in this action; and
- (f) Awarding counterplaintiffs any further and additional relief as the Court deems just and proper.



**DEMAND FOR JURY TRIAL**

Apotex, Inc. and Apotex Corp. demand trial by jury for all issues triable by jury as a matter of right.

DATED: December 28, 2007  
Miami, FL

Respectfully submitted,

s/. Stephen J. Bronis  
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*Attorneys for Apotex Corp. and Apotex, Inc.*



CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing served by mail on December 28, 2007 on all counsel of record on the attached service list.

s/. Jennifer Coberly  
Jennifer Coberly



SERVICE LIST  
Case No. 07-61800-CIV-MORENO/SIMONTON

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# **EXHIBIT P**



UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and  
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and  
APOTEX CORP.,

Defendants.

**ANSWER OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT, AFFIRMATIVE  
DEFENSES AND AMENDED COUNTERCLAIMS<sup>1</sup>**

Defendants, Apotex Inc. and Apotex Corp., Answer the Complaint of Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") as follows:

**Parties**

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

**ANSWER:** Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 1 of the Complaint, and on that basis deny such averments.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

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<sup>1</sup> This pleading is identical to the pleading filed December 28, 2007, except that certain inadvertent typographical errors in paragraphs 9, 11, 15 and 16 of the Counterclaims have been corrected.



**ANSWER:** Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 2 of the Complaint, and on that basis deny such averments.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9; that Apotex, Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings, Inc. and that Apotex, Inc. manufactures numerous drugs that are sold and used in this judicial district. Apotex, Inc. and Apotex Corp. deny that Apotex Pharmaceutical Holdings, Inc. is a wholly-owned subsidiary of Apotex Holdings, Inc. Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments in Paragraph 3 with respect to whether its products are sold and used “throughout the United States”, and on that basis deny such averments.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326, but deny that Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.



**Nature of the Action**

5. This is a civil action for the infringement of United States Patent No. 4,661,491 (“the ‘491 patent”) (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Plaintiffs’ Complaint purports to bring this action for the alleged infringement of United States Patent No. 4,661,491 (“the ‘491 patent”) and that a copy of the ‘491 patent appears to be attached to the Complaint as Exhibit A. Apotex, Inc. and Apotex Corp. also admits that Plaintiffs purport to bring this action based on the Patent Laws of the United States, 35 U.S.C. §1 *et seq.*

**Jurisdiction and Venue**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the subject matter of this action.

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortuous action of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff Sanofi-Aventis U.S., which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

**ANSWER:** Apotex Corp. admits that this Court has personal jurisdiction over it in this District for the purposes of this action. For purposes of this action, Apotex, Inc. does not contest the Court’s personal jurisdiction over it. Apotex, Inc. and Apotex Corp. deny the averments against them to the extent they assert Apotex, Inc. and Apotex Corp. committed or aided, abetted, contributed to and/or participated in the commission of the referenced acts of patent



infringement or that Plaintiff Sanofi-Aventis U.S. has been injured or otherwise harmed through any alleged tortious acts of Defendants. As to the remaining averments, Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to their truth or falsity and on that basis deny such averments.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

**ANSWER:** For purposes of this action, Apotex, Inc. does not contest the Court's jurisdiction over it, but denies the alleged basis for personal jurisdiction asserted in this paragraph, including that Apotex Corp. is Apotex, Inc.'s "sister corporation and agent."

9. This Court has personal jurisdiction over Apotex Corp. By virtue of the fact that, *inter alia*, Apotex Inc. is a Florida corporation.

**ANSWER:** Apotex Corp. does not contest the Court's jurisdiction over it in this action, but denies that Apotex Inc. is a Florida corporation. Apotex Corp. does have its principal place of business in Florida at 2400 North Commerce Parkway, Weston, Florida 33326.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that venue is proper in this judicial district.

#### **The '491 Patent**

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.



**ANSWER:** Apotex, Inc. and Apotex Corp. admit that the '491 patent issued on April 28, 1987, but deny that this patent was duly and legally issued. Apotex, Inc. and Apotex Corp. admit that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® and that Sanofi-Aventis U.S. is listed as the Applicant for NDA No. 21-287. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of Paragraph 11 of the Complaint, and on that basis deny such averments.

**Acts Giving Rise to this Action**  
**Infringement of the '491 Patent by Defendants**

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. filed its ANDA No. 79-013 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10mg strength. Defendants admit that Apotex, Inc. seeks FDA approval to market the proposed product identified in its ANDA prior to the expiration of the '491 patent. The remaining averments of this paragraph are denied.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j) (2) (A) (vii) (IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j) (2) (A) (vii) (IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. provided Plaintiffs with notice of its ANDA No. 79-013, that such notice satisfied all statutory and regulatory



requirements and that Plaintiffs received notice on or about October 25, 2007. The remaining averments of this paragraph are denied.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j) (2) (A) (vii) (IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 14 of the Complaint.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 15 of the Complaint.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j) (2) (A) (vii) (IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 16 of the Complaint.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j) (2) (A) (vii) (IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 17 of the Complaint. Further, this allegation has no basis in fact or law and unless it is withdrawn, Defendants will seek sanctions under Rule 11 of the Federal Rules of Civil Procedure.



18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 18 of the Complaint.

19. Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007 Civil action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

**ANSWER:** Apotex, Inc. and Apotex Corp. admit that Plaintiffs filed an action against them in the District of Delaware. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the averments concerning Plaintiffs' intentions, knowledge or beliefs, and on that basis deny such averments. Apotex, Inc. and Apotex Corp. deny that Apotex, Inc. is subject to personal jurisdiction in the Delaware action and deny that judicial economy would be promoted by proceeding with the Delaware action as opposed to this action.

#### **GENERAL DENIAL**

Any allegation in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' Complaint, Defendants deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or any relief whatsoever.



**AFFIRMATIVE DEFENSES**

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following affirmative defenses to the Complaint:

**FIRST AFFIRMATIVE DEFENSE**

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of Apotex Inc.'s ANDA No. 79-013 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '491 patent, either literally or under the doctrine of equivalents.

**SECOND AFFIRMATIVE DEFENSE**

The claims of the '491 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112.

**THIRD AFFIRMATIVE DEFENSE**

Plaintiffs have failed to state a claim on which relief can be granted. Defendants reserve their right to assert any and all additional defenses and counterclaims that discovery may reveal.

**AMENDED COUNTERCLAIMS**

Apotex Inc. and Apotex Corp., (collectively "counterplaintiffs") for their Counterclaims against Sanofi-Aventis ("Sanofi-Aventis") and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S.") (the counter-defendants will be referred to herein collectively as "Sanofi"), allege as follows:



### **The Parties**

1. Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Ontario, Canada M9L 1 T9.
2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida 33326.
3. Sanofi-Aventis U.S. has alleged that it is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
4. Sanofi-Aventis has alleged that it is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

### **Jurisdiction and Venue**

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter “Hatch-Waxman Amendments”), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter “MMA”).
6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338 (a).
7. The Court has personal jurisdiction over Sanofi because Sanofi has availed themselves to the rights and privileges of this forum by suing counterplaintiffs in this District



and because Apotex Corp. conducts substantial business in and has regular systematic contacts with this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400 (b).

**Patents-in-Suit**

9. On or about April 28, 1987, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 4,661,491 (“the ’491 patent”), entitled “ALFUZOSINE COMPOSITIONS AND USE” to Francois Regnier.

10. Sanofi-Aventis purports to own and to have the right to enforce the ’491 patent.

11. On or about November 21, 2000, the PTO issued U.S. Patent No. 6,149,940 (“the ’940 patent”) entitled “TABLET WITH CONTROLLED RELEASE OF ALFUZOSINE CHLORHYDRATE” to Laurretta Maggi, Ubaldo Conte, Busto Arisizio, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau and Clemence Rauch-Desanti.

12. Sanofi-Aventis purports to own an interest in ’940 patent and on information and belief has an exclusive license and the right to unilaterally bring and proceed with lawsuits to enforce the ’940 patent in its own name.

13. Sanofi-Aventis U.S. is identified as the owner of New Drug Application No. 21-287 on Uroxatral brand alfuzosin hydrochloride extended release tablets. The ’491 patent and the ’940 patent are listed in the Orange Book for Uroxatral.

14. Sanofi has attempted to enforce the ’940 patent against multiple other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets.

15. Apotex has submitted an abbreviated new drug application (ANDA) No. 79-013 to the FDA. Apotex Inc.’s ANDA seeks FDA approval for the commercial use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet.



16. Pursuant to 21 U.S.C. § 355(j) (2) (B) (ii) and 21 C.F.R. § 314.95, Apotex, Inc. has certified to Sanofi that the '491 patent and the '940 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use of sale of the new drug for which ANDA 79-013 is submitted.

17. On or about August 14, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '940 patent.

18. On or about October 15, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '491 patent.

19. On or about December 10, 2007, Sanofi sued Apotex Inc and Apotex Corp in this District alleging infringement of the '491 patent under 35 U.S.C. § 271 (e)(2)(A).

20. Counterplaintiffs have a reasonable apprehension of being sued by Sanofi for alleged infringement of the '940 patent because, *inter alia*, Apotex, Inc. has served Sanofi with its Paragraph IV certification letter asserting that the '940 patent was not infringed, Sanofi has sued more than ten other ANDA holders seeking to market alfuzosin hydrochloride extended release tablets for alleged infringement of the '940 patent, and Sanofi already has sued counterplaintiffs for infringement of the '491 patent in this court.

21. As a result of Sanofi's actions in listing of the '491 and '940 patents in the Orange Book and in suing counterplaintiffs for infringement of the '491 patent, counterplaintiffs are presently prevented from selling alfuzosin hydrochloride extended release tablets and are being



injured as a result. Counterplaintiffs seek patent certainty with respect to the '491 and '940 patents and certainty regarding the legal rights relating to Apotex, Inc.'s ANDA through a judicial declaration that the '491 and '940 patents are not infringed by the alfuzosin hydrochloride extended release tablets identified in Apotex, Inc.'s ANDA, or that the patents are invalid.

22. A real, actual, and justiciable controversy exists between counterplaintiffs and Sanofi regarding the invalidity of the '491 and '940 patents and counterplaintiffs' non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

**COUNT I**  
**(Declaration of Non-Infringement of the '491 Patent)**

23. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-22.

24. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

25. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.



**COUNT II**  
**(Declaration of Invalidity of the '491 Patent)**

26. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-25.

27. The claims of the '491 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

28. Counterplaintiffs are entitled to a declaration that the claims of the '491 patent are invalid.

**COUNT III**  
**(Declaration of Non-infringement of the '940 Patent)**

29. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-28.

30. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

31. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

**COUNT IV**  
**(Declaration of Invalidity of the '940 Patent)**

32. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-31.



33. The claims of the '940 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

34. Counterplaintiffs are entitled to a declaration that the claims of the '940 patent are invalid.

**REQUEST FOR RELIEF**

WHEREFORE, Defendants Apotex Inc. and Apotex Corp. respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Sanofi-Aventis and Sanofi-Aventis US as follows:

- (a) Declaring that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent;
- (b) Declaring that the claims of the '491 patent are invalid;
- (c) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent;
- (d) Declaring that the claims of the '940 patent are invalid;
- (e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding counterplaintiffs their attorneys' fees, costs, and expenses in this action; and
- (f) Awarding counterplaintiffs any further and additional relief as the Court deems just and proper.



**DEMAND FOR JURY TRIAL**

Apotex, Inc. and Apotex Corp. demand trial by jury for all issues triable by jury as a matter of right.

DATED: January 2, 2008  
Miami, FL

Respectfully submitted,

s/. Stephen J. Bronis  
Stephen J. Bronis  
sbronis@zuckerman.com  
Fla. Bar No. 145970  
Jennifer Coberly  
jcoberly@zuckerman.com  
Fla. Bar No. 930466  
**ZUCKERMAN SPAEDER LLP**  
201 South Biscayne Blvd., Suite 900  
Miami, FL 33131  
Tel: 305-358-5000  
Fax: 305-579-9749

and

s/. Robert B. Breisblatt  
Robert B. Breisblatt  
rbreisblatt@welshkatz.com  
Fla. Bar No. 145928  
Steven E. Feldman  
Sherry L. Rollo  
**WELSH & KATZ, LTD.**  
120 South Riverside Plaza  
Chicago, IL 60606  
Tel: 312-655-1500  
Fax: 312-655-1501

*Attorneys for Apotex Corp. and Apotex, Inc.*



CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing served by mail on January 2, 2008 on all counsel of record on the attached service list.

s/. Jennifer Coberly  
Jennifer Coberly



SERVICE LIST  
Case No. 07-61800-CIV-MORENO/SIMONTON

Alfred John Saikali  
e-mail: asaikali@shb.com  
Shook Hardy & Bacon  
201 South Biscayne Blvd., Suite 2400  
Miami, FL 33131  
Tel: 305-358-5171  
Fax: 305-358-7470  
*Attorneys for Plaintiffs,*  
*Sanofi-Aventis and Sanofi-Aventis, U.S. LLC*



# **EXHIBIT Q**



**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA**

SANOFI-AVENTIS and	)	
SANOFI-AVENTIS U.S. LLC,	)	
	)	Case No. 07 C 61800
Plaintiffs,	)	Judge Moreno
	)	
	)	
vs.	)	Magistrate Judge Simonton
	)	
APOTEX INC. and	)	
APOTEX CORP.,	)	
	)	
Defendants.	)	

**DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S RULE 26(a) (1)  
INITIAL DISCLOSURES**

Pursuant to Fed. R. Civ. P. 26(a) (1), Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") make the following initial disclosures based on the information available to Defendants at this time. Defendants reserve the right to supplement these disclosures.

**A. The Name and, If Known, the Address and Telephone Number of Each Individual Likely to Have Discoverable Information that the Disclosing Party May Use to Support Its Claims or Defenses, Unless Solely for Impeachment, Identifying the Subjects of the Information**

1. Francois Regnier  
6, rue de la Source  
54000 Nancy, France

Subjects: The subject matter claimed in U.S. Patent No. 4,661,491; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.



2. Helmuth A. Wegner  
Wegner & Bretschneider  
PO Box 18218  
Washington, DC 20036-8218  
(202) 887-0400

Subjects: The preparation of the application and prosecution of the application for U.S. Patent No. 4,661,491; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

3. Laretta Maggi  
Via Folperti N.3  
I-27100 Pavia  
Italy

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

4. Ubaldo Conte  
Via Treviglio n.6  
I-20052 Busto Arisizio  
Italy

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

5. Pascal Grenier  
23a rue du Marechal de Saxe  
68300 Saint Louis  
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.



6. Guy Vergnault  
9 rue du Bois Vert  
68300 Saint Louis  
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

7. Alain Dufour  
42 Avenue de Saxe  
75007 Paris  
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

8. Francois Xavier Jarreau  
5 rue L. Herve  
78000 Versailles  
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.



9. Clemence Rauch-Desanti  
19 rue Prix d'Amerique  
77330 Ozoire la Ferriere  
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

10. D. Douglas Price  
Jacobson, Price, Holman 7 Stern, PLLC  
400 7<sup>th</sup> Street, N.W., Suite 600  
Washington, DC 20004  
(202) 638-6666

Subjects: The preparation of the application and prosecution of the application for U.S. Patent No. 6,149,940; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

11. Bernice Tao  
Apotex Inc.  
c/o Welsh & Katz, Ltd.  
120 S. Riverside Plaza, 22<sup>nd</sup> Floor  
Chicago, IL 60606

Subjects: Information on the non-infringement of the patents at issue.

12. Any other person substantively involved in the preparation and/or prosecution of U.S. Patent Nos. 4,661,491 and 6,149,940.

**B. A Copy of, or a Description by Category and Location of, All Documents, Data Compilations, and Tangible Things that Are in Possession, Custody, or Control of the Party and that the Disclosing Party May Use to Support Its Claims or Defenses, Unless Solely for Impeachment**

Defendants identify the following documents, compilations and things that

Defendants may use to support their claims or defenses:

1. Prior art and other documents and things identified in Apotex Inc's August 14, 2007 and October 15, 2007 Paragraph IV letters.



2. Documents related to U.S. Patents No. 4,661,491 and 6,149,940, including the patents themselves, the prosecution histories, and the prior art cited during the prosecution of the patents.

3. Abbreviated New Drug Application No. 79-013.

**C. A Computation of Any Category of Damages Claimed by the Disclosing Party, Making Available for Inspection and Copying as Under Rule 34 and Documents or Other Evidentiary Material, Not Privileged or Protected from Disclosure, in Which Such Computation Is Based, Including Materials Bearing on the Nature and Extent of Injuries Suffered.**

Defendants are not seeking damages at this time.

**D. For Inspection and Copying as Under Rule 34 Any Insurance Agreement Under Which Any Person Carrying on an Insurance Business May Be Liable to Satisfy Part or All of a Judgment Which May Be Entered in the Action or to Indemnify or Reimburse for Payments Made to Satisfy Judgment**

Defendants have not identified any documents of this type at this time.

Dated: January 17, 2008



Stephen J. Bronis

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*Attorneys for Apotex Corp and Apotex Inc.*



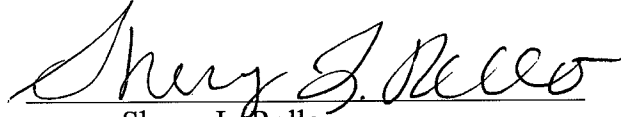
**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by electronic and U.S. mail to the following:

Alfred John Saikali  
asaikali@shb.com  
Shook Hardy & Bacon  
201 S Biscayne Boulevard  
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Miami, FL 33131-4332

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153 E 53rd Street  
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January 17, 2008

  
Sherry L. Rollo



# **EXHIBIT R**



**KIRKLAND & ELLIS LLP**  
AND AFFILIATED PARTNERSHIPS

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January 17, 2008

**By Federal Express and  
Electronic Mail**

Steven E. Feldman, Esq.  
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120 South Riverside Plaza  
Chicago, Illinois 60606  
sefeldman@welshkatz.com

Stephen J. Bronis, Esq.  
Zuckerman Spaeder LLP  
201 South Biscayne Blvd., Suite 900  
Miami, Florida 33131  
sbronis@zuckerman.com

Re: *Sanofi-aventis et al. v. Apotex Inc. et al.*,  
Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Steven and Stephen:

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby provide the following disclosures required by the Court's Pretrial Order Setting Conference dated January 3, 2008 Pursuant to the Local Rules 16.1.B.1 & 16.1.B.2 of the Southern District of Florida, Miami Division to Defendants Apotex Inc. and Apotex Corp. (collectively "Defendants").<sup>1</sup> These disclosures are based upon information reasonably and presently available to sanofi-aventis, without the benefit of formal discovery, production of documents, or any meaningful disclosures from the Defendants. Accordingly, sanofi-aventis reserves the right to amend and/or supplement these disclosures in its formal Initial Disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1), that are currently due on January 31, 2008, or any supplements or amendments to those disclosures as its investigation and discovery proceeds in this action.

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<sup>1</sup> The parties held a conference call on January 15, 2008 pursuant to the Court's January 3, 2008 Pretrial Order Setting Conference and discussed issues related to some aspects of that Order and sanofi-aventis's request for a meet and confer regarding moving the case to the Complex Track from the Expedited Track.



## KIRKLAND &amp; ELLIS LLP

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 Stephen J. Bronis, Esq.  
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Sanofi-aventis expects that the parties will continue to meet and confer with respect to these issues as well as the parties' other obligations under Federal Rule of Civil Procedure 26(f) while jointly preparing the Joint Conference Report pursuant to S.D. Fla. L.R. 16.1.B.2 that is currently due on January 31, 2008.

Disclosures

**(1) Documents (S.D. Fla. L.R. 16.1.B.1 and 2) -** The parties shall determine the procedure for exchanging a copy of or a description by category and location of all documents and other evidence that is reasonably available and that a party expects to offer or may offer if the need arises. Fed. R. Civ. P. 26(a)(1)(B).

**Response:** Sanofi-aventis lists the following categories of documents and the location of such documents that it expects to offer or may offer if the need arises in this litigation based on its investigation to date. The parties are continuing to meet and confer concerning the form of and procedure for document production in this action. Sanofi-aventis reserves the right to supplement and/or amend this list as its investigation and discovery proceeds in this action.

Location	Description
sanofi-aventis 174 avenue de France 75635 Paris cedex 13	Certain documents concerning the marketing and sales of Uroxatral®, licensing administration related to Uroxatral®, United States Patent Nos. 4,661,491 and 6,149,940 and their prosecutions, and other business records.
sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807	Certain documents concerning the marketing and sales of Uroxatral®, United States Patent Nos. 4,661,491 and 6,149,940 and their prosecutions, and other business records.
sanofi-aventis 46 quai de la Rapée 75012 Paris	Certain documents concerning the marketing of Uroxatral®.
sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex	Certain documents concerning the conception and reduction to practice of the inventions claimed in United States Patent Nos. 4,661,491 and 6,149,940, design and development of Uroxatral®, clinical trials related to



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Location	Description
	Uroxatral®, and regulatory activities related to Uroxatral®.
sanofi-aventis Research & Development 371 rue du Pr Joseph Blayac 34184 Montpellier cedex 04	Certain documents concerning pharmacokinetic studies related to Uroxatral®.
sanofi-aventis Research & Development 2-8 rue de Rouen Zone industrielle de Limay 78440 Porcheville	Certain documents concerning animal studies related to Uroxatral®.
Sanofi Winthrop Industrie 30-36 avenue Gustave Eiffel BP 27166 37071 Tours cedex 2	Certain documents concerning the industrial design and manufacture of Uroxatral®.
sanofi-aventis U.S. LLC 9 Great Valley Parkway Malvern, PA 19355	Certain documents concerning the industrial design of, manufacture of, and regulatory filings for Uroxatral®.
sanofi-aventis U.S. LLC 300-400 Somerset Corporate Boulevard Bridgewater, NJ 08807-0912	Certain documents concerning the marketing of Uroxatral®.

(1)(a) Documents include computations of the nature and extent of any category of damages claimed by the disclosing party unless the computations are privileged or otherwise protected from disclosure. Fed. R. Civ. P. 26(a)(1)(C).

**Response:** Under 35 U.S.C. § 271(e)(4)(C), damages are not available with respect to the patent claims in this action unless Defendants violate applicable laws and regulations and engage in any commercial manufacture, use, importation, offer to sell or sale of the generic product described in ANDA 79-013 within the United States. To sanofi-aventis's knowledge, Defendants have not engaged in any such commercial activity and, as a result, damages are not available with respect to the patent claims in this action at this time. Accordingly, sanofi-aventis is unable to calculate any damages at this time.



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 Stephen J. Bronis, Esq.  
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(1)(b) Documents include insurance agreements which may be at issue with the satisfaction of the judgment. Fed. R. Civ. P. 26(a)(1)(D).

**Response:** Sanofi-aventis is not presently aware of any documents that relate to section 1(b).

(2) **List of Witnesses** - The parties shall exchange the name, address and telephone number of each individual known to have knowledge of the facts supporting the material allegations of the pleading filed by the party. Fed. R. Civ. P. 26(a)(1)(A). The parties have a continuing obligation to disclose this information.

**Response:** Sanofi-aventis identifies the following individuals known to have knowledge of the facts supporting the material allegations of the pleadings filed by sanofi-aventis, based on its investigation to date. Sanofi-aventis reserves the right to supplement and/or amend this list as its investigation and discovery proceeds in this action.

Individual and Contact Information	Subject of Information Known
Alaux, Gerard sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel.: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.
Andre, Frederic sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel.: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.



## KIRKLAND &amp; ELLIS LLP

Steven E. Feldman, Esq.

Stephen J. Bronis, Esq.

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Individual and Contact Information	Subject of Information Known
<p>Barry, Meredith sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Barry, Patrick sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Boisson, Gilles sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain license administration activities related to Uroxatral®.</p>
<p>Borneman, James sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>



## KIRKLAND &amp; ELLIS LLP

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 Stephen J. Bronis, Esq.  
 January 17, 2008  
 Page 6

Individual and Contact Information	Subject of Information Known
Bretschneider, Barry E. Morrison & Foerster LLP, 1650 Tysons Boulevard Suite 400 McLean, VA 22102 Tel.: +1 202 887 1500	Knowledge of the prosecution of United States Patent No. 4,661,491.
Brohier, Sylvie sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge of certain clinical trials related to Uroxatral®.
Burg, Christine sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00  Contact through sanofi-aventis's counsel of record.	Knowledge of certain license administration activities related to Uroxatral®.
Conte, Ubaldo Università degli Studi di Pavia Strada Nuova, 65 - 27100 Pavia Italy Tel.: +39.0382.9811	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.



## KIRKLAND &amp; ELLIS LLP

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 Stephen J. Bronis, Esq.  
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 Page 7

Individual and Contact Information	Subject of Information Known
<p>Depaire, Olivier          Sanofi Winthrop Industrie          30-36 avenue Gustave Eiffel          BP 27166          37071 Tours cedex 2          France          Tel.: +33 (0)2 47 42 35 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain industrial development activities related to Uroxatral®.</p>
<p>DeSieno, Mark          sanofi-aventis U.S. LLC          9 Great Valley Parkway          Malvern, PA 19355          Tel.: +1 610 889 8600</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain industrial development activities related to Uroxatral®.</p>
<p>Dufour, Alain          Boulogne-Billancourt, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Egan, Beth          sanofi-aventis U.S. LLC          300-400 Somerset Corporate Boulevard          Bridgewater, NJ 08807-0912          United States          Tel.: +1 908 243 6000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>



## KIRKLAND &amp; ELLIS LLP

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Individual and Contact Information	Subject of Information Known
<p>Gardella, Mark sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain life cycle management activities related to Uroxatral®.</p>
<p>Gaydos, Mark sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain regulatory and marketing activities related to Uroxatral®.</p>
<p>Grenier, Pascal Address unknown</p> <p>Contact through Constance S. Huttner or Ryan P. Farley at Buchanan Ingersoll &amp; Rooney PC.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Jacobson Jr., Harvey Jacobson Holman PLLC 400 Seventh St., NW Washington, DC 20004 Tel.: +1 202 638 6666</p>	<p>Knowledge of the prosecution of United States Patent No. 6,149,940.</p>
<p>Jarreau, Francois Xavier Paris, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>



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Individual and Contact Information	Subject of Information Known
Kugel, Dominique sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00  Contact through sanofi-aventis's counsel of record.	Knowledge of certain prosecution activities related to United States Patent No. 6,149,940.
Legathe, Agnes sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge of certain regulatory activities related to Uroxatral®.
Lewis, Gareth sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.
Maggi, Lauretta Università degli Studi di Pavia Strada Nuova, 65 - 27100 Pavia Italy Tel.: +39.0382.9811	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.



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Individual and Contact Information	Subject of Information Known
<p>Marcelli, Mihaela sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain license administration activities related to Uroxatral®.</p>
<p>Ogle, Mary sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Papp, Diane sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Penfornis, M.D. Catherine sanofi-aventis Research &amp; Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain regulatory activities related to Uroxatral®.</p>



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Individual and Contact Information	Subject of Information Known
<p>Rauch-Desanti, Clemence sanofi-aventis Research &amp; Development 371 rue du Pr Joseph Blayac 34184 Montpellier cedex 04 France Tel.: +33 (0)4 67 10 67 10</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Regnier, Francois, M.D. Nancy, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 4,661,491, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Sant, M.D., Granham sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities and medical affairs related to Uroxatral®.</p>
<p>Sieuw, Pascal sanofi-aventis 46 quai de la Rapée 75601 Paris cedex 12 France Tel.: +33 (0)1 55 71 30 07</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Thouret-Lemaitre, Elizabeth Paris, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain prosecution activities related to United States Patent Nos. 4,661,491 and 6,149,940.</p>



## KIRKLAND &amp; ELLIS LLP

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 Page 12

Individual and Contact Information	Subject of Information Known
Tina, Jay sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000  Contact through sanofi-aventis's counsel of record.	Knowledge of certain clinical trials related to Uroxatral® and BPH registry.
Trussardi, Claire sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge of certain clinical trials related to Uroxatral®.
Vergnault, Guy Address unknown  Contact through Constance S. Huttner or Ryan P. Farley at Buchanan Ingersoll & Rooney PC.	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.
Wegner, Harold C. Foley & Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007 Tel.: +1 202 672 5300	Knowledge of the prosecution of United States Patent No. 4,661,491.
Wegner, Helmuth A. address unknown	Knowledge of the prosecution of United States Patent No. 4,661,491.

(3) **Settlement Discussions (S.D. Fla. L.R. 16.1.B.2)**- The parties shall discuss the nature and basis of their claims and defenses and the possibilities for a prompt settlement or resolution of the case.

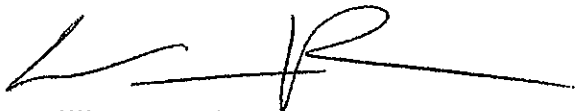


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Stephen J. Bronis, Esq.  
January 17, 2008  
Page 13

**Response:** On January 15, 2008, the parties discussed the potential for settlement with respect to this action and concluded that a settlement was unlikely now or at any date in the near future.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. T. Vuk', with a long horizontal stroke extending to the right.

William T. Vuk

cc (via email only):  
Jack Blumenfeld, Esq.  
Jennifer Coberly, Esq.  
Richard L. Horwitz, Esq.  
Edward A. Moss, Esq.  
Alfred J. Saikali, Esq.



# EXHIBIT S



UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
MIAMI DIVISION

Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and  
SANOFI-AVENTIS U.S. LLC,  
Plaintiffs,

vs.

APOTEX INC. and  
APOTEX CORP.,  
Defendants.

\_\_\_\_\_ /

**PLAINTIFFS' INITIAL DISCLOSURES PURSUANT TO RULE 26(A)(1)**

Pursuant to Federal Rules of Civil Procedure 26(a)(1), Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis"), based upon information reasonably available to sanofi-aventis at this time, hereby provides its initial disclosures to Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex").

These disclosures are in furtherance of sanofi-aventis's disclosures pursuant to the Court's Pretrial Order Setting Conference dated January 3, 2008 Pursuant to the Local Rules 16.1.B.1 & 16.1.B.2 of the Southern District of Florida, Miami Division and are based upon information reasonably and presently available to sanofi-aventis, without the benefit of formal discovery, production of documents, or any meaningful disclosures from the Defendants. Accordingly, sanofi-aventis reserves the right to amend and/or supplement these disclosures as its investigation and discovery proceeds in this action.



**Initial Disclosures**

**Rule 26.(a)(1)(A)(i)** the name and, if known, the address and telephone number of each individual likely to have discoverable information—along with the subjects of that information—that the disclosing party may use to support its claims or defenses, unless the use would be solely for impeachment.

**Response:** Sanofi-aventis identifies the following individuals likely to have discoverable information and whom sanofi-aventis may use to support its claims or defenses, based on its investigation to date. Sanofi-aventis reserves the right to supplement and/or amend this list as its investigation and discovery proceeds in this action.

<b>Individual and Contact Information</b>	<b>Subject of Information Known</b>
Alaux, Gerard sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel.: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.
Alexander, Michael D. sanofi-aventis U.S. LLC Route #202-206/P.O. Box 6800 Bridgewater, New Jersey 08807-0800 Tel.: +1 610 889 8458  Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain activities related to the '491 patent.
Andersson, K. E. address unknown	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Andre, Frederic sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel.: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.



Individual and Contact Information	Subject of Information Known
<p>Barry, Meredith sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Barry, Patrick sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Boisson, Gilles sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain license administration activities related to Uroxatral®.</p>
<p>Borneman, James sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Bretschneider, Barry E. Morrison &amp; Foerster LLP, 1650 Tysons Boulevard Suite 400 McLean, Virginia 22102 Tel.: +1 202 887 1500</p>	<p>Knowledge of the prosecution of United States Patent No. 4,661,491.</p>
<p>Brohier, Sylvie sanofi-aventis Research &amp; Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain clinical trials related to Uroxatral®.</p>



Individual and Contact Information	Subject of Information Known
<p>Burg, Christine sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain license administration activities related to Uroxatral®.</p>
<p>Icilio Caverio, Ph. D. Lucca, Italy</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Ceccardi, R. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Conte, Ubaldo Università degli Studi di Pavia Strada Nuova, 65 - 27100 Pavia Italy Tel.: +39.0382.9811</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Depaire, Olivier Sanofi Winthrop Industrie 30-36 avenue Gustave Eiffel BP 27166 37071 Tours cedex 2 France Tel.: +33 (0)2 47 42 35 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain industrial development activities related to Uroxatral®.</p>
<p>DeSieno, Mark sanofi-aventis U.S. LLC 9 Great Valley Parkway Malvern, PA 19355 Tel.: +1 610 889 8600</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain industrial development activities related to Uroxatral®.</p>
<p>Darkes, Paul R. sanofi-aventis U.S. LLC 9 Great Valley Parkway Malvern, Pennsylvania 19355 Tel.: +1 610 889 8600</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain activities related to the '491 patent.</p>



Individual and Contact Information	Subject of Information Known
Doyle, P.T. address unknown	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Dufour, Alain Boulogne-Billancourt, France  Contact through sanofi-aventis's counsel of record.	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.
Egan, Beth sanofi-aventis U.S. LLC 300-400 Somerset Corporate Boulevard Bridgewater, New Jersey 08807-0912 Tel.: +1 908 243 6000  Contact through sanofi-aventis's counsel of record.	Knowledge of certain marketing activities related to Uroxatral®.
Ek, A. address unknown	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Galzin, Anne-Marie address unknown  Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Gardella, Mark sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000  Contact through sanofi-aventis's counsel of record.	Knowledge of certain life cycle management activities related to Uroxatral®.
Gaydos, Mark sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000  Contact through sanofi-aventis's counsel of record.	Knowledge of certain regulatory and marketing activities related to Uroxatral®.
Grenier, Pascal Muttenez, Switzerland  Contact through Constance S. Huttner or Ryan P. Farley at Buchanan Ingersoll & Rooney PC.	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.



Individual and Contact Information	Subject of Information Known
Hedlund, H. address unknown	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Jacobson Jr., Harvey Jacobson Holman PLLC 400 Seventh St., NW Washington, DC 20004 Tel.: +1 202 638 6666	Knowledge of the prosecution of United States Patent No. 6,149,940.
Jarreau, Francois Xavier Versailles, France  Contact through sanofi-aventis's counsel of record.	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.
Kugel, Dominique sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00  Contact through sanofi-aventis's counsel of record.	Knowledge of certain prosecution activities related to United States Patent No. 6,149,940.
Langer, Salomon Z. Tel Aviv, Israel  Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Legathe, Agnes sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge of certain regulatory activities related to Uroxatral®.
Lewis, Gareth sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77  Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.
Maggi, Lauretta Università degli Studi di Pavia Strada Nuova, 65 - 27100 Pavia Italy Tel.: +39.0382.9811	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.



Individual and Contact Information	Subject of Information Known
<p>Manoury, Phillipe, Ph.D. Sceaux, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Marcelli, Mihaela sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain license administration activities related to Uroxatral®.</p>
<p>Margonato, A. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Mayo, M. E. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Oehler, Ross J. Collegeville, Pennsylvania</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain activities related to the '491 patent.</p>
<p>Ogle, Mary sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Papp, Diane sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Penfornis, M.D. Catherine sanofi-aventis Research &amp; Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain regulatory activities related to Uroxatral®.</p>



Individual and Contact Information	Subject of Information Known
<p>Pimoule, Carmen address unknown</p> <p>Contact through sanofi-aventis's counsel of record</p>	<p>Knowledge of the information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Poopalasingham, N. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Price, D. Douglas 1134 Randolph Road McLean, Virginia 22101 Tel.: +1 703 442 3364</p>	<p>Knowledge of the prosecution of United States Patent No. 6,149,940.</p>
<p>Rauch, Clemence sanofi-aventis Research &amp; Development 371 rue du Pr Joseph Blayac 34184 Montpellier cedex 04 France Tel.: +33 (0)4 67 10 67 10</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Regnier, Francois, M.D. Nancy, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 4,661,491, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Rigatti, P. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Ronchi, F. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Rossini, B. M. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Sant, M.D., Granham sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities and medical affairs related to Uroxatral®.</p>



Individual and Contact Information	Subject of Information Known
<p>Sieuw, Pascal sanofi-aventis 46 quai de la Rapée 75601 Paris cedex 12 France Tel.: +33 (0)1 55 71 30 07</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Tao, Bernice Director, Regulatory Affairs US Apotex Inc. 150 Signet Drive Toronto, Ontario M9L 1T9</p>	<p>Knowledge of certain activities related to the preparation and filing of ANDA 79-013 and the infringement of the patents at issue.</p>
<p>Thouret-Lemaitre, Elizabeth Paris, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain prosecution activities related to United States Patent Nos. 4,661,491 and 6,149,940.</p>
<p>Tina, Jay sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain clinical trials related to Uroxatral® and BPH registry.</p>
<p>Trussardi, Claire sanofi-aventis Research &amp; Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain clinical trials related to Uroxatral®.</p>
<p>Vergnault, Guy Muttenez, Switzerland</p> <p>Contact through Constance S. Huttner or Ryan P. Farley at Buchanan Ingersoll &amp; Rooney PC.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Wegner, Harold C. Foley &amp; Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007 Tel.: +1 202 672 5300</p>	<p>Knowledge of the prosecution of United States Patent No. 4,661,491.</p>
<p>Whitfield, H. N. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>



Individual and Contact Information	Subject of Information Known
Authors of the prior art references cited within the Paragraph IV Certification notice letters regarding ANDAs related to alfuzosin hydrochloride 10 mg extended release tablets received by sanofi-aventis from Actavis South Atlantic LLC, Aurobindo Pharma Ltd., Barr Laboratories, Inc., Mylan Pharmaceuticals Inc., Ranbaxy Laboratories Limited, Sun Pharmaceutical Industries, Inc., Teva Pharmaceuticals USA, Inc., and Torrent Pharmaceuticals Limited.	Knowledge concerning certain information contained within or related to art cited in the Paragraph IV Certification notice letters sent to sanofi-aventis regarding ANDAs related to alfuzosin hydrochloride 10 mg extended release tablets.

Upon information and belief, certain past and/or present employees and agents of Defendants having substantial involvement in the decision to file, the preparation and submission of Abbreviated New Drug Application 79-013; and the research, development and formulation pertaining to the proposed generic product defined by ANDA 79-013.

**Rule 26.(a)(1)(A)(ii):** a copy—or a description by category and location—of all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody, or control and may use to support its claims or defenses, unless the use would be solely for impeachment.

**Response:** Sanofi-aventis lists the following categories and locations of documents, electronically stored information and tangible things that sanofi-aventis has in its possession, custody, or control and may use to support its claims of defenses in this litigation based on its investigation to date. The parties are continuing to meet and confer concerning the form of and procedure for document production in this action. Sanofi-aventis reserves the right to supplement and/or amend this list as its investigation and discovery proceeds in this action.

Location	Description
sanofi-aventis 174 avenue de France 75635 Paris cedex 13	Certain documents concerning the marketing and sales of Uroxatral®, licensing administration related to Uroxatral®, United States Patent Nos. 4,661,491 and 6,149,940 and their prosecutions, and other business records.
sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807	Certain documents concerning the marketing and sales of Uroxatral®, United States Patent Nos. 4,661,491 and 6,149,940 and their prosecutions, and other business records.



Location	Description
sanofi-aventis 46 quai de la Rapée 75012 Paris	Certain documents concerning the marketing of Uroxatral®.
sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex	Certain documents concerning the conception and reduction to practice of the inventions claimed in United States Patent Nos. 4,661,491 and 6,149,940, design and development of Uroxatral®, clinical trials related to Uroxatral®, and regulatory activities related to Uroxatral®.
sanofi-aventis Research & Development 371 rue du Pr Joseph Blayac 34184 Montpellier cedex 04	Certain documents concerning pharmacokinetic studies related to Uroxatral®.
sanofi-aventis Research & Development 2-8 rue de Rouen Zone industrielle de Limay 78440 Porcheville	Certain documents concerning animal studies related to Uroxatral®.
Sanofi Winthrop Industrie 30-36 avenue Gustave Eiffel BP 27166 37071 Tours cedex 2	Certain documents concerning the industrial design and manufacture of Uroxatral®.
sanofi-aventis U.S. LLC 9 Great Valley Parkway Malvern, PA 19355	Certain documents concerning the industrial design of, manufacture of, and regulatory filings for Uroxatral®.
sanofi-aventis U.S. LLC 300-400 Somerset Corporate Boulevard Bridgewater, NJ 08807-0912	Certain documents concerning the marketing of Uroxatral®.

Upon information and belief, Jagotec AG and SkyePharma PLC may also be in possession of documents, electronically stored information and tangible things potentially relevant to Apotex's counterclaims and, to the extent that the Court has jurisdiction over those counterclaims, sanofi-aventis's defenses to those counterclaims, including United States Patent No. 6,149,940 and its prosecution, development and use of the Geomatrix® technology, and agreements between Jagotec and/or SkyePharma and sanofi-aventis or its predecessors:

JAGOTEC AG  
Seestrasse 91  
CH-6052 Hergiswil, Switzerland



JAGOTEC AG  
Eptingerstrasse 51  
Muttenz 4132  
Switzerland

SkyePharma PLC  
105 Piccadilly  
W1J 7NJ  
Great Britain

**Rule 26.(a)(1)(A)(iii)** a computation of each category of damages claimed by the disclosing party—who must also make available for inspection and copying as under Rule 34 the documents or other evidentiary material, unless privileged or protected from disclosure, on which each computation is based, including materials bearing on the nature and extent of injuries suffered.

**Response:** Under 35 U.S.C. § 271(e)(4)(C), damages are not available with respect to the patent claims in this action unless Defendants violate applicable laws and regulations and engage in any commercial manufacture, use, importation, offer to sell or sale of the generic product described in ANDA 79-013 within the United States. To sanofi-aventis's knowledge, Defendants have not engaged in any such commercial activity and, as a result, damages are not available with respect to the patent claims in this action at this time. Accordingly, sanofi-aventis is unable to calculate any damages at this time.

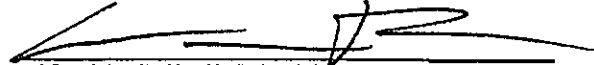
**Rule 26.(a)(1)(A)(iv)** for inspection and copying as under Rule 34, any insurance agreement under which an insurance business may be liable to satisfy all or part of a possible judgment in the action or to indemnify or reimburse for payments made to satisfy the judgment.

**Response:** Sanofi-aventis states that it is not aware of any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or to indemnify or reimburse for payments made to satisfy any such judgment.



Dated: January 31, 2008

Respectfully submitted,



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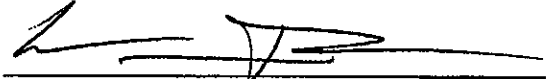
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*Attorneys for Plaintiffs sanofi-aventis and  
sanofi-aventis U.S. LLC*



**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing was served by U.S. Mail and by electronic mail on January 31, 2008, on all counsel or parties of record on the attached service list.



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**SERVICE LIST**

**SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL**

**Case No.: 07-61800-CIV-Moreno/Simonton**

**United States District Court  
Southern District of Florida  
(Miami Division)**

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# EXHIBIT T



Not Reported in F.Supp.2d

Page 1

Not Reported in F.Supp.2d, 2006 WL 850916 (N.D.Ill.)

(Cite as: Not Reported in F.Supp.2d)

**H**

Abbott Laboratories v. Mylan Pharmaceuticals, Inc.  
N.D.Ill.,2006.

Only the Westlaw citation is currently available.

United States District Court,N.D. Illinois, Eastern  
Division.

ABBOTT LABORATORIES, an Illinois Corpora-  
tion, Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC., a West  
Virginia Corporation, Defendant.

**No. 05 C 6561.**

March 28, 2006.

Daniel E. Reidy, James R. Daly, Jason G.  
Winchester, Melissa Rose Beiting, Jones Day,  
Chicago, IL, for Plaintiff.

John A. Leja, McGuire Woods LLP, Chicago, IL,  
Richard S. Meyer, McGuire Woods LLP, McLean,  
VA, Timothy H. Kratz, McGuire Woods LLP, At-  
lanta, GA, for Defendant.

*MEMORANDUM OPINION AND ORDER*

KENDALL, J.

\*1 Plaintiff Abbott Laboratories, Inc.  
("Abbott") brings this action against Defendant  
Mylan Pharmaceuticals, Inc. ("Mylan"), alleging  
patent infringement under 35 U.S.C. § 271(e)(2).  
Defendants move to dismiss the complaint for lack  
of personal jurisdiction or, in the alternative, to  
transfer the case on the basis of convenience to the  
Northern District of West Virginia. Because this  
district has general jurisdiction over Mylan, and be-  
cause interests of justice and convenience of the  
parties do not warrant transfer to West Virginia, the  
Court denies the motion.

*Facts*

On a motion to dismiss under Rule 12(b)(2),  
the Court takes all well-pled facts in the complaint  
as true. *Pickrel v. City of Springfield*, 45 F.3d 1115,  
1117 (7th Cir.1995). The following facts are drawn

from Abbott's complaint ("Complaint at ¶ \_\_\_\_").

Abbott holds two patents for Sodium Hydrogen  
Divalproate Oligomer, Patent No. 4,988,731 and  
Patent No. 5,212,326, each of which is set to expire  
on January 29, 2008. Complaint at ¶ 7-9. On Au-  
gust 4, 2000, the Food and Drug Administration  
("FDA") approved Abbott's New Drug Application  
for Depakote, a trademarked product. *Id.* at ¶ 6.  
After the FDA approved Depakote, the FDA listed  
the drug on the "Approved Drug Products with  
Therapeutic Equivalence Evaluations" list and asso-  
ciated the two patents with Depakote. *Id.* at ¶¶ 6,11.

On April 12, 2005, Mylan notified Abbott that  
it had filed an Abbreviated New Drug Application  
("ANDA") with the FDA to make a generic equi-  
valent of Depakote. *Id.* at ¶ 12-13. On October 5,  
2005, Mylan notified Abbott that Mylan had modi-  
fied its ANDA to include a "Paragraph IV" certifi-  
cation, in which Mylan challenged the validity and/  
or enforceability of Abbott's two patents for De-  
pakote, as permitted by 21 U.S.C. §  
355(j)(2)(A)(vii)(IV). *Id.* at ¶ 14-15.

By statute, filing a Paragraph IV certification  
as part of an ANDA is an act of patent infringe-  
ment. *See* 35 U.S.C. § 271(e)(2). Once a patent  
holder has received notice that a Paragraph IV cer-  
tification has been filed that implicates one or more  
of its patents, the patent holder has 45 days in  
which to file suit for patent infringement or the  
ANDA will be approved immediately and the pat-  
ent protection will be lost. *See* 35 U.S.C. §  
271(e)(5); 21 U.S.C. 355(j)(5)(B)(iii). On Novem-  
ber 18, 2005 Abbott filed two suits for patent in-  
fringement: one in the Northern District of West  
Virginia, where Mylan has its corporate headquar-  
ters, and one in the Northern District of Illinois,  
where Abbott has its corporate headquarters. Mylan  
has moved this Court to dismiss the case before it  
for lack of personal jurisdiction or, in the alternat-  
ive, to transfer the case to West Virginia where the  
other suit is pending. Abbott has moved the court in  
West Virginia to stay the proceedings before it



pending resolution of the motion before this Court.

### *Standard*

The party seeking to establish jurisdiction bears the burden to make a *prima facie* showing that the forum has personal jurisdiction over the defendant. *Euromarket Designs, Inc. v. Crate & Barrel Ltd.*, 96 F.Supp.2d 824, 833 (N.D.Ill.2000); *Electronics for Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1349 (Fed.Cir.2003). When deciding a matter of jurisdiction, a court may look to affidavits and exhibits submitted by each party. *Turnock v. Cope*, 816 F.2d 332, 333 (7th Cir.1987), *superceded on other grounds*. Because this case alleges patent infringement, the Court's analysis of personal jurisdiction is guided by Federal Circuit law rather than Seventh Circuit law. *Coolsavings.com, Inc. v. IQ Commerce Corp.*, 53 F.Supp.2d 1000, 1002 (N.D.Ill.1999) citing *3D Systems, Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1377 (Fed.Cir.1998).

\*2 A federal district court applies the personal jurisdiction rules of the forum state. *3D Systems*, 160 F.3d at 1376. The Illinois long-arm statute permits courts to assert personal jurisdiction over a non-resident defendant on any basis permitted by the Illinois and the United States constitutions. See 735 ILCS 5/2-209; *Central States, Southeast and Southwest Areas Pension Fund v. Reimer Express World Corp.*, 230 F.3d 934, 939 (7th Cir.2000). When analyzing personal jurisdiction under Illinois law, there is no substantive difference between the due process limitations on personal jurisdiction set forth by the U.S. Constitution and by the Illinois Constitution. *Hyatt Int'l. Corp. v. Coco*, 302 F.3d 707, 715 (7th Cir.2002).<sup>FN1</sup>

FN1. Although the Seventh Circuit does not hear appeals from cases involving allegations of patent infringement, the Seventh Circuit has addressed the legal parameters of personal jurisdiction in Illinois with far greater frequency than the Federal Circuit. This Court will look to Seventh Circuit law as persuasive authority, particularly in the area of general jurisdiction.

A plaintiff demonstrates personal jurisdiction over a non-resident defendant through a two-part inquiry: (1) the state's long-arm statute permits personal jurisdiction over the defendant, and (2) that jurisdiction complies with due process. *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1359 (Fed.Cir.2001). Illinois' long-arm statute permits jurisdiction over a non-resident defendant in two ways. If the defendant's contacts with the forum state are the same contacts as those at issue in the suit, the defendant may be subject to specific jurisdiction. *Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc.* 148 F.3d 1355, 1359 (Fed.Cir.1998); *Graco, Inc. v. Kremlin, Inc.*, 558 F.Supp. 188, 191-92 (N.D.Ill.1982). If the defendant's contacts with the forum state are not the same contacts as those giving rise to the suit, the plaintiff must meet a higher burden and show that the plaintiff has "continuous, permanent, ongoing and systematic" contact with a forum. See *LSI Indus., Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1375 (Fed.Cir.2000); *Milligan v. Soo Line R.R. Co.*, 775 F.Supp. 277, 279 (N.D.Ill.1991). This contact, also known in Illinois as "doing business" in the state of Illinois, will make the defendant amenable to all suits in the state, including suits arising from conduct that did not occur in the forum state. *Milligan*, 775 F.Supp. at 279.

If Illinois has personal jurisdiction over a non-resident defendant, the assertion of jurisdiction must comport with "fair play and substantial justice"-that is, a showing that a suit in the state against the defendant would be fair and reasonable. *Red Wing Shoe*, 148 F.3d at 1358-59. This second stage has also been described as a showing that the defendant's conduct in the forum state is such that the defendant should "reasonably anticipate being haled into court there." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 287, 100 S.Ct. 559, 62 L.Ed.2d 490 (1980).

In this case, Abbott does not allege that Illinois has specific jurisdiction over Mylan. The issue giving rise to this suit is Mylan's Paragraph IV ANDA, the filing of which triggered a statutory right to sue for patent infringement. See 21 U.S.C. §



355(j)(2)(A)(vii)(IV). Mylan has not yet taken any action that normally would constitute infringement, such as the manufacture or sale of the infringing product; rather, the statute governing ANDAs specifically creates a “highly artificial” statutory act of patent infringement at the moment of Paragraph IV filing. *See* 35 U.S.C. § 271(e)(2); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990) (statute intended to create a “highly artificial” act of patent infringement to allow subject matter jurisdiction prior to the sale of the generic drug). No part of the preparation of the ANDA or the filing the ANDA took place in Illinois, and there has been no other injury to Abbott, so there is no basis for asserting specific jurisdiction over Mylan.

\*3 Abbott instead has sued Mylan in Illinois under principles of general jurisdiction, providing evidence that Mylan is “doing business” in Illinois to the extent that it has such systematic and continuous contact with Illinois that it may be sued in this forum for any activity, including activities that are not connected to Illinois.

#### *Doing Business*

There is no all-inclusive test for determining whether a non-resident defendant has such systematic and continuous contact with the forum state as to subject it to general jurisdiction. *See Graco*, 558 F.Supp. at 192. Courts typically have looked to the presence of officers, persons, licenses, or sales activities within Illinois as evidence of systematic contact. *See Milligan*, 775 F.Supp. at 279-80 (discussing test); *Graco*, 558 F.Supp. at 192 (relying on volume of sales). Although courts typically look to these factors, Illinois requires an independent determination in each case of whether, on the basis of all the circumstances, it would be fair to subject the defendant to jurisdiction here. *Alderson v. Southern Co.*, 321 Ill.App.3d 832, 254 Ill.Dec. 514, 747 N.E.2d 926, 941 (Ill.App.Ct.2001).

Abbott concedes that Mylan does not have a physical office or agent in Illinois, as verified via

affidavit attached to Mylan's Motion to Dismiss. Abbott relies on five different types of contact that Mylan maintains with Illinois: Mylan's volume of sales and percentage of revenue in Illinois, Mylan's ongoing contracts with companies in Illinois, an Illinois distribution license maintained by Mylan, Mylan's informational website presence, and Mylan's amenability to prior litigation in this district.

Abbott's primary evidence that Mylan has systematic and continuous contact with Illinois are figures obtained from Mylan's documents showing that Mylan distributed substantial quantities of pharmaceuticals to wholesalers and retailers in Illinois, and gained substantial revenues from those sales. Abbott provides information about sales revenue both in absolute monetary terms and as a percentage of the overall revenues of the company and of the company's parent.<sup>FN2</sup> The revenue from sales in Illinois is substantial and consistent over the five years prior to the suit. Distribution of a defendant company's products in Illinois in sufficient quantities, and with substantial revenues, may subject a non-resident defendant to general jurisdiction. *See Graco*, 558 F.Supp. at 192 (finding that defendant was “doing business” by shipping a large percentage of its equipment through its Illinois subsidiary); *see also Connelly v. Uniroyal, Inc.*, 75 Ill.2d 393, 27 Ill.Dec. 343, 389 N.E.2d 155, 160 (Ill.1979) (directing products to Illinois “on a regular basis and in substantial numbers” sufficient to create general jurisdiction).

FN2. As portions of these briefs are subject to an agreed Protective Order and were filed under seal, the Court does not refer to specific information or numbers submitted by the parties. The Court considered all relevant confidential information submitted by the parties, but references the submitted data only generally. *See Pepsico, Inc. v. Redmond*, 46 F.3d 29, 30 (7th Cir.1995) (directing district courts to prepare opinions for general circulation while referencing protected materials indirectly).



Illinois courts have not created a consistent standard as to the necessary showing of volume of sales or revenues before exercising general jurisdiction over a non-resident defendant. Unfortunately, most courts have opted for general descriptions of sufficiency rather than specific data. See *Graco*, 558 F.Supp. at 192 (“large percentage” sufficient to support general jurisdiction); *Connelly*, 329 N.E.2d at 406 (jurisdiction appropriate when product came to Illinois “on a regular basis and in substantial numbers”); *McGill v. Gigantex Technologies Co., Ltd.*, 2005 WL 3436403, \*3 (N.D.Ill.Dec.12, 2005) (“small percentage” not sufficient). In those cases that did provide numerical figures, however, Mylan's volume of sales exceeds the volumes that have been sufficient to support general jurisdiction in the past. See, e.g., *Hubbell*, 232 F.3d at 1375 (“millions of dollars of sales” conducted “over the past several years” and “broad distribution network” sufficient for general jurisdiction); *Milligan*, 775 F.Supp. at 280-81 (Illinois sales totaling 3-5% of annual company revenues sufficient for general jurisdiction). The Court finds that Mylan's volume of sales, and the revenues derived from those sales, constitute substantial and continued contact with Illinois supporting a finding of general jurisdiction in this forum.

\*4 It is not relevant whether the sales went through a distributor before reaching Illinois; general jurisdiction extends to both direct and indirect sales into the forum state. See *Graco*, 558 F.Supp. at 193 (“Because [defendant] receives substantial economic benefit from its regular activity within the state, it can be said to be ‘doing business’ here even though its dealings here are indirect.”); *Connelly*, 389 N.E.2d at 405 (“A manufacturer's economic relationship with a state does not necessarily differ in substance, nor should its amenability to jurisdiction necessarily differ, depending on whether it deals directly or indirectly with residents of the state”); see also *Giotis v. Apollo of the Ozarks, Inc.*, 800 F.2d 660, 667 (7th Cir.1986) (“A seller at the head of a distribution network thus satisfies the requisite foreseeability of due process where it ‘delivers its products into the stream of commerce with the expectation that [these products] will be

purchased by consumers in the forum state” ’). Abbott has shown sufficiently, via Mylan's own documents, that a substantial percentage of Mylan's revenues come from sales to the state of Illinois.

Mylan does not object to the veracity of Abbott's evidence of sales and revenue. Rather, Mylan argues that Abbott's evidence does not support general jurisdiction, because a showing of general jurisdiction in the absence of specific jurisdiction places a higher burden on the plaintiff. In support of its position, Mylan relies on *Bearry v. Beech Aircraft Corporation*, a case from the Fifth Circuit in which the court denied general jurisdiction over an action in which it did not have specific jurisdiction, despite the plaintiffs' evidence of substantial sales into the forum state. 818 F.2d 370, 374-5 (5th Cir.1987). Mylan draws from *Bearry* the notion that general jurisdiction in the absence of specific jurisdiction requires additional evidence besides sales and revenues, such as contract negotiation within the forum or subsidiaries. The Court finds *Bearry* to be unpersuasive, as binding case precedent within this circuit and this state has found general jurisdiction on the basis of sales and revenues in sufficient quantities, and the Court finds that those quantities have been surpassed by Mylan in this case.

Additionally, Abbott has addressed the concerns raised in *Bearry*, and similar concerns raised in cases in this district, by providing supporting evidence of Mylan's other contacts with this forum to supplement its evidence of sales and revenues. Those cases in Illinois that have declined to exercise general jurisdiction in Illinois on the basis of the volume of sales did so because the non-resident defendant had no other contact with the forum state. See *McGill*, 2005 WL 3436403 at \*3 (sales totaling less than 3% of defendant's total revenues insufficient to support general jurisdiction without other evidence); *Hot Wax, Inc. v. Stone Soap, Inc.*, 1999 WL 183776, \*4 (N.D.Ill. Mar.25, 1999) (where volume of sales small, court will exercise jurisdiction only if defendant also targeted advertisements). As discussed in the following section, Abbott provides additional evidence of other contacts between Mylan and Illinois to bolster its contention



that general jurisdiction in this case is appropriate.

*Supporting information*

\*5 Abbott supports the evidence of substantial sales and revenues from Illinois with several additional contacts between Mylan and Illinois. While each of these pieces of evidence standing alone might not subject Mylan to general jurisdiction in Illinois, they support the Court's finding that Mylan has conducted business in Illinois to such an extent that the Court may infer that Mylan has availed itself of the laws of Illinois and that it would be fair to permit them to be sued in this state.

1 *License.* Mylan holds two current "Licensed Drug Distributor" licenses from the Illinois Department of Financial and Professional Regulation. Illinois requires any "person, partnership, corporation or business firm engaging in the wholesale distribution of human prescription drugs within [Illinois]" to receive a license from this department. Wholesale Drug Distribution Licensing Act, 225 ILCS 120/5 (defining scope of the act). Mylan has held the public licenses since 1999. Abbott Mot. in Opp., Ex. C.

A license from the Illinois Secretary of State, which may then act as an agent for service of process on a defendant, traditionally establishes a state's jurisdiction over the license holder. See *Polansky v. Anderson*, 2005 WL 3557858 at \*4 (N.D.Ill.Dec.29, 2005). Although Mylan's licenses come from an Illinois regulatory agency, and do not automatically establish general jurisdiction, they do represent an ongoing contact with the state of Illinois, and support an inference that Mylan intended to do business within the state.

2. *Mylan's Website.* Mylan maintains a national website for informational and advertising purposes only. The website does not sell any of Mylan's products or conduct business transactions. However, the website has interactive components, as customers may submit inquiries to Mylan for additional information about Mylan products. Abbott argues that the website should be viewed in con-

junction with the other evidence offered in support of jurisdiction, as supporting evidence that jurisdiction over Mylan in Illinois is proper.

The seminal case discussing the Internet and personal jurisdiction, *Zippo Manufacturing Company v. Zippo Dot Com, Inc.*, held that websites should be examined on a "sliding scale" when determining personal jurisdiction. 952 F.Supp. 1119, 1124 (W.D.Pa.1997). In cases where a defendant clearly does business over the Internet, including entering into contracts, personal jurisdiction is proper. *Id.* On the other side, if the defendant's website is completely passive and allows no interaction with a customer, personal jurisdiction is not proper. *Id.* The "middle ground" set forth in *Zippo*, which best describes Mylan's website, "is occupied by interactive Web sites where a user can exchange information with the host computer" but cannot purchase products; these sites should be evaluated on a case-by-case basis. *Id.*, see also *Neomedia Techs., Inc. v. AirClic, Inc.*, 2004 WL 848181 at \*4 (N.D.Ill. Apr.16, 2004) (applying the *Zippo* test to personal jurisdiction analysis in Illinois).

\*6 A hybrid website alone will not support general jurisdiction over a defendant corporation. *Infosys Inc. v. Billingnetwork.com, Inc.*, 2003 WL 22012687 at \*4 (N.D.Ill. Aug.23, 2003). But a website can form part of the basis for general jurisdiction, and two recent cases in this district exercised personal jurisdiction over a non-resident defendant after viewing a hybrid website in connection with the company's other contacts in the state. See *Publications Int'l, Ltd. v. Burke/Triolo, Inc.*, 121 F.Supp.2d 1178, 1183 (N.D.Ill.2000) (finding general jurisdiction on basis of a hybrid interactive website plus extensive distribution of materials within Illinois); *George S. May Int'l. Co. v. Xcentric Ventures, LLC*, 409 F.Supp.2d 1052, 1059-60 (N.D.Ill.2006) (listing sales and solicitations, in addition to a hybrid website, and finding general jurisdiction over non-resident defendant). While Mylan's website alone might not support personal jurisdiction, the presence of the website adds weight to the Court's finding that general jurisdiction in this case is proper.



3. *Contracts in Illinois.* Abbott and Mylan agree that Mylan has pending contracts with approximately twenty separate entities shipping Mylan's products into Illinois, or in some cases repackaging Mylan products at their plants in Illinois. Seven of these companies have their principal places of business in Illinois. Abbott argues that these contracts form an additional basis for finding that Mylan has a continuing relationship with parties in the forum state.

Mylan responds that the contracts do not support personal jurisdiction because defendants are not subject to jurisdiction in a forum based on contracts with out-of-state entities who did business in the forum, citing *Red Wing Shoe*, 148 F.3d 1355. In *Red Wing Shoe*, the state of Minnesota did not have personal jurisdiction over a non-resident defendant that licensed its product to 34 companies doing business in the state. Mylan's reliance on *Red Wing Shoe* is misplaced, however, because the court in *Red Wing Shoe* specifically noted that none of the 34 licensees were incorporated in the forum state or had their principal places of business in the state. *Id.* at 1357-58. Abbott has alleged, and Mylan has conceded, the seven of the main contracts identified by Abbott for distribution in Illinois are companies that have their principal places of business within the forum state.

4. *Prior Litigation within this District.* Finally, Abbott raises Mylan's history as a defendant in this court, and its decisions in the past not to contest personal jurisdiction, as further evidence that general jurisdiction over Mylan is proper. Neither party offers case law on this point. Unlike the evidence offered by Abbott with respect to the sales, the website, the license, and the contracts, prior litigation within the state of Illinois does not support a finding of general jurisdiction. The Court has reviewed the cases in this district in which Mylan is or was a defendant, none contain a finding as to whether Illinois has general jurisdiction over Mylan. This Court will not second-guess the strategy of Mylan's attorneys to accept service in those particular cases. However, as discussed below, the fact that Mylan has litigated cases by con-

sent in this forum in the past, including cases of ANDA patent infringement brought by Abbott, weakens Mylan's argument that litigation in this forum is inconvenient.

#### *Due Process*

\*7 Once a movant has shown that a non-resident defendant has systematic and continuous contacts with Illinois to support general jurisdiction, the Court must look to whether the decision to exercise jurisdiction comports with due process. Under the Due Process Clause of the Fourteenth Amendment, an Illinois court may exercise jurisdiction over a non-resident defendant if the defendant has "certain minimum contacts with [the state] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *International Shoe Co. v. Washington*, 326 U.S. 310, 316, 66 S.Ct. 154, 90 L.Ed. 95 (1945) (citations omitted). Once a plaintiff has demonstrated that there are minimum contacts, the burden shifts to the defendant to show "a compelling case that the presence of some other considerations would render jurisdiction unreasonable." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477, 105 S.Ct. 2174, 85 L.Ed.2d 528 (1985).

In determining the reasonableness of jurisdiction, the Federal Circuit looks to five factors: (1) the burden on the defendant, (2) the interests of the forum state, (3) the plaintiff's interest in obtaining relief, (4) the interstate judicial system's interest in obtaining the most efficient resolution of controversies, and (5) the shared interest of the several states in furthering fundamental substantive social policies. *Electronics For Imaging*, 340 F.3d at 1352. In this case, Mylan has not demonstrated an unreasonable burden from litigating this case in Illinois. The burden on Mylan to litigate in Chicago is greater than it would be if this case remained in West Virginia, but Mylan has litigated other major cases in this district on prior occasions. Illinois has an interest in protecting its citizens from patent infringement, and Abbott certainly has an interest in obtaining relief from patent infringement. Neither



the interstate judicial system nor the shared interest of the states will be affected by assertion of jurisdiction in this case, because all states are governed by the same body of patent law. *See id.* (addressing the same five factors in a patent infringement cases).

#### *Transfer of Venue*

As an alternative to dismissal for lack of personal jurisdiction, Mylan requests that this Court transfer the action under 28 U.S.C. § 1404(a) to the Northern District of West Virginia, Mylan's home district and the site of the parallel suit filed by Abbott. Mylan offers two main arguments in support of its request to transfer the instant action to West Virginia: first, it would be more convenient to conduct the litigation in West Virginia; and second, the case before the Court is duplicative of the case before the court in West Virginia. Because the Court does not find that this case merits a transfer for the convenience of the parties, and because the Court respects Mylan's need to file duplicate litigation due to statutory ambiguity, the request to transfer is denied.

A party may request that a court transfer a case to another venue "for the convenience of the parties and witnesses, in the interest of justice." 28 U.S.C. § 1404(a). In patent cases, courts normally give great weight to the plaintiff's choice of forum when a defendant requests a transfer of venue. *Hollyanne Corp. v. TFT, Inc.*, 199 F.3d 1304, 1307 n. 2 (Fed.Cir.1999). Mylan argues that it is more convenient to the witnesses to have this case transferred to the Northern District of West Virginia, where another identical action is presently pending. The Court agrees that this action would be more convenient for Mylan if it were pending in West Virginia-Mylan's home district. However, the action would be more convenient for Abbott if it were to proceed before this Court-Abbott's home district, because the evidence supporting the validity of Abbott's patent will involve documents and witnesses from Abbott's corporate headquarters, located in the Chicago area. In arguing for the relative conveni-

ence of West Virginia, Mylan relies primarily on the presence of the documents and witnesses pertaining to the preparation of the ANDA at its corporate headquarters. In a case where all of the witnesses of the defendant will be its employees, however, the location is not as important a factor as it would be if the witnesses were not under the control of the defendant. *Id.* at 1307 n. 2.

\*8 Additionally, Mylan's argument that its convenience outweighs Abbott's convenience loses persuasiveness in light of the fact that Mylan has litigated two different ANDA/patent infringement suits, for different pharmaceuticals, against Abbott in this forum, without contesting personal jurisdiction. The considerations of convenience in this case balance one another; Mylan has not met its burden to show that transfer of the case to West Virginia would be more convenient for the parties and witnesses than litigation here. *See generally Abbott Laboratories v. Zenith Laboratories, Inc.*, 1995 WL 117984 (N.D.Ill. Mar.16, 1995) (denying transfer of venue to defendant's district in patent infringement case arising out of an ANDA).

Second, Mylan requests that this Court dismiss this case on the grounds that Abbott should not be permitted to bring parallel suits in different jurisdictions. While the Court is troubled by the apparently increasing number of "protective" suits filed in ANDA-related patent infringement actions such as this case, the Court cannot fault Abbott for its litigation strategy in the face of an ambiguous statute that remains devoid of court interpretation. Abbott does not seek double recovery or have any desire to litigate parallel suits, and has requested a stay in the suit pending in the Northern District of West Virginia. Patent holders have a strict statutory 45-day window in which to file suit after the patent holder receives notice that a generic company has filed an ANDA. *See* 21 U.S.C. 355(j)(5)(B)(iii). The statute is silent, and the courts have not clarified, whether the patent holder loses its right to sue for patent infringement in the event its suit is dismissed for lack of personal jurisdiction after the 45-day period has expired.



Between service and briefing of a motion to dismiss for lack of personal jurisdiction, it would be nearly impossible for a court to deliver a ruling within 45 days so as to permit a patent holder to file another suit. Indeed, a generic manufacturer defendant in this circumstance will likely make the strategic decision to delay filing a motion for lack of personal jurisdiction as long as possible, in the hopes that the 45-day period will expire before the action is dismissed on personal jurisdiction grounds. Therefore, patent holders are stuck between a jurisdictional rock and hard place: file suit in the forum of choice but risk losing patent protection if the suit is dismissed for personal jurisdiction, or file suit in the only known safe forum and incur all the inconvenience of litigating the matter in a distant location. However, as the Court finds that it has general jurisdiction over the defendant in this case, there is no need to reach this issue.<sup>FN3</sup>

FN3. It is possible that 28 U.S.C. § 1631 would solve this problem by permitting a court to transfer an action filed by a patent holder such as Abbott for lack of personal jurisdiction. Section 1631 would preserve the original date of filing in the improper jurisdiction, allowing patent holders to preserve their right to sue, while also allowing courts to ensure that the action moved forward in the appropriate forum. However, the circuits have split over whether § 1631 applies to personal jurisdiction (as opposed to subject matter jurisdiction) and neither the Seventh Circuit nor the Federal Circuit have addressed the issue. See *Carpenter-Lenski v. Ramsey*, No. 99-3367, 2000 WL 287651 at \*2 (7th Cir.2000) (acknowledging the split in authority over this issue).

#### *Conclusion*

Abbott has established a *prima facie* case that Mylan maintains systematic and continuous contact with Illinois, through its sales and revenues in Illinois, supported by its contractual connections,

Illinois licenses, and interactive website. Mylan has not shown that it would be unreasonable to bring Mylan into court here, or that there it would be more convenient for the parties or witnesses to transfer this case to West Virginia. Therefore, the Court denies the motion to dismiss for lack of personal jurisdiction or, in the alternative, transfer the matter to West Virginia.

\*9 So ordered.

N.D.Ill.,2006.

Abbott Laboratories v. Mylan Pharmaceuticals, Inc.  
Not Reported in F.Supp.2d, 2006 WL 850916  
(N.D.Ill.)

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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

CHAMBERS OF  
HAROLD A. ACKERMAN  
SENIOR JUDGE

UNITED STATES DISTRICT COURT  
POST OFFICE BOX 999  
NEWARK, NEW JERSEY 07101-0999

November 16, 2006

TO ALL COUNSEL OF RECORD

Re: *Adams Respiratory Therapeutics, Inc. v. Mutual Pharm. Holdings Co.*, Civil Action No. 06-4700

Dear Counsel:

I have reviewed the letters from counsel regarding Plaintiff's request that this Court hold an immediate status conference "to resolve issues relating to an identical case pending in the Eastern District of Pennsylvania." (Pl.'s Letter to Court 11/9/06 at 1.) After careful consideration, this Court denies Plaintiff's request.

Plaintiff Adams Respiratory Therapeutics, Inc. ("Adams") filed the instant action in this Court on October 2, 2006. Prior to filing its Complaint in this Court, Adams learned that Defendant Mutual Pharmaceutical Holdings, Co. ("Mutual") had challenged this Court's personal jurisdiction in an unrelated case, *Eisai Co., Ltd. v. Mutual Pharmaceutical*, Civ. No. 06-3613 (D.N.J. filed August 3, 2006). As Adams notes, Eisai's response to Mutual's personal jurisdiction challenge has been stayed pending jurisdictional discovery.

Understandably concerned that a successful challenge to the personal jurisdiction of this Court by Mutual in the *Eisai* action conceivably could cause Adams problems in its own suit against Mutual, Adams filed an identical action in the Eastern District of Pennsylvania two days after filing in this Court. This was necessary, from Adams's viewpoint, to preserve "certain substantive rights provided under the Hatch-Waxman Act." (Pl.'s Letter to Court 11/9/06 at 2.) Subsequent to filing in Pennsylvania, Adams moved that court to stay proceedings there pending the outcome of the jurisdictional issue in this Court. The Eastern District of Pennsylvania denied the motion to stay and the case is proceeding apace in that District.

Adams requests that I exercise my discretion as the Court in which the first action was filed and enjoin the Eastern District of Pennsylvania from proceeding with the case filed in that jurisdiction. (Pl.'s Letter to Court 11/9/06 at 3 (citing *Triangle Conduit & Cable, Inc. v. National Electric Prod. Corp.*, 125 F.2d 1008, 1009-10 (3d Cir. 1942); *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir. 1941)).) While I recognize that I have the power to direct the Eastern District of Pennsylvania to stay its related, subsequently-filed proceeding, I decline to exercise that power.



The “first-filed rule” is intended to prevent duplicative litigation, but I do not believe the rule was intended to provide a single plaintiff the opportunity to institute identical suits in various jurisdictions and then put all but the first one on the back burner until such time as the plaintiff deems convenient. *See Triangle*, 125 F.2d at 1008-09 (reversing district court of first-filed case for not enjoining second case filed by *defendant* in another district).

Presumably, Adams would like me to decide the *Eisai v. Mutual* personal jurisdiction issue, which would give Adams some indication of whether it would prevail on the same issue, especially now that Mutual has raised the same personal jurisdiction issue in the *Adams v. Mutual* case as well. If Adams were satisfied with my ruling in the *Eisai v. Mutual* case, then, ostensibly, it would voluntarily dismiss the Pennsylvania action and proceed with its identical case in this Court. Alternatively, now that Mutual has moved this Court to dismiss for lack of personal jurisdiction, it would be of great benefit to Adams if I decided that motion out of turn.

With respect to the *Eisai v. Mutual* motion, I cannot decide a motion that has not been fully briefed and that is stayed pending jurisdictional discovery. With respect to the more recently filed motion by Mutual in this case, I am disinclined to make any decision of such importance in haste. Moreover, as I am sure counsel can appreciate, my docket contains many other motions that were filed well in advance of this one that are of equal importance to the respective parties. While I am sympathetic to Adams’s predicament, the situation is of its own making. If Adams wants to proceed in its first choice of forum, it knows how to unilaterally effectuate that circumstance.

This Court hereby DENIES Adams’s request for an immediate status conference and hereby DENIES Adams’s request that this Court enjoin the Eastern District of Pennsylvania action.

SO ORDERED

s/ Harold A. Ackerman  
U.S.D.J.

HAA:amb







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Page 1

Slip Copy, 2007 WL 4284877 (W.D.Mich.)

(Cite as: Slip Copy)

Adams Respiratory Therapeutics, Inc. v. Perrigo Co.

W.D.Mich., 2007.

Only the Westlaw citation is currently available.

United States District Court, W.D.

Michigan, Southern Division.

ADAMS RESPIRATORY THERAPEUTICS, INC.,

Adams Respiratory Operations, Inc. and Adams Respiratory Products, Inc., Plaintiffs,

v.

PERRIGO COMPANY, L. Perrigo Company and Perrigo Research and Development Company, Defendants.

No. 1:07-cv-993.

Dec. 3, 2007.

Thomas R. Behm, Gruel Mills Nims & Pylman LLP, Grand Rapids, MI, for Plaintiffs.

Richard A. Gaffin, Miller Canfield Paddock & Stone PLC, Grand Rapids, MI, for Defendants.

### OPINION

GORDON J. QUIST, District Judge.

\*1 The Court has before it Plaintiffs' ("Adams") Motion to Stay the proceedings in this case pending the outcome of similar litigation in the District of New Jersey. For the following reasons, the Court will grant Adams' motion.

#### I. Facts and Procedural History

In August 2007, Defendants ("Perrigo") sent Adams a notice that it had filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration to produce a generic version of Adams' patented drug product, Mucinex®. Under the Hatch-Waxman Act of 1984, an owner of a patented drug may file an action in federal court within 45 days of receiving an ANDA notice in order to obtain a 30-month stay of approval of the generic drug. 21 U.S.C. § 355(c)(3)(c). In its letter of notice, Perrigo consented to be sued in the West-

ern District of Michigan. However, Adams filed suit against Perrigo in the District of New Jersey on September 27, 2007. Due to its belief that Perrigo would challenge jurisdiction in New Jersey, Adams also filed suit in this Court on October 5, 2007. Adams claims that it filed suit in this Court only to protect itself should it lose the jurisdictional challenge in New Jersey after the 45 day filing period had elapsed. It now appears that Perrigo has consented to personal jurisdiction in New Jersey but has filed a motion in the District of New Jersey to transfer the proceedings to this Court.

#### II. Legal Standard

Although not found in the Federal Rules of Civil Procedure, "the power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes in its docket with economy of time and effort for itself, for counsel and for litigants." *Landis v. North Am. Co.*, 299 U.S. 248, 254-55, 57 S.Ct. 163, 166, 81 L.Ed. 153 (1936). The party seeking a stay "must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to someone else." *Id.*, 57 S.Ct. at 163. Therefore, "the burden is on the party seeking the stay to show that there is a pressing need for delay, and that neither the other party nor the public will suffer harm from entry of the order." *Ohio Envtl. Council v. U.S. Dist. Court*, 565 F.2d 393, 396 (6th Cir.1977).

Also influencing the Court's analysis of Adams' motion is the first-to-file rule. The first-to-file rule generally states "that when actions involving nearly identical parties and issues have been filed in two different district courts, the court in which the first suit was filed should generally proceed to judgment." *Zide Sport Shop of Ohio, Inc. v. Ed Tobergate Assoc., Inc.*, 16 F.App'x 433, 437 (6th Cir.2001) (internal quotation and citation omitted). Courts have the discretion to dispense with the rule, and factors that weigh against its application



“include extraordinary circumstances, inequitable conduct, bad faith, anticipatory suits, and forum shopping.”*Id.*

### III. Analysis

\*2 At the outset, the Court notes that “[t]he case law on ANDA litigation is not settled, and there is no definitive guidance to those district court judges who are charged with handling ‘protective’ lawsuits such as the one at issue here.”*Schering Co. v. Caraco Pharm. Laboratories, Ltd.*, No. 06-14386, 2007 WL 1648908, at \*2 (E.D.Mich. June 6, 2007). Thus, it is unclear how the first-to-file rule applies in ANDA lawsuits. *Id.* In the absence of guidance, the Court should examine the prejudice to either party in light of the purpose of the first-to-file rule and principles of comity.

First, going forward with both actions simultaneously would waste judicial resources and present the possibility of conflicting rulings or judgments.*PDL Biopharma, Inc. v. Sun Pharm. Indus., Ltd.*, No. 07-11709, 2007 WL 2261386, at \*2 (E.D.Mich. Aug.6, 2007). Moreover, simultaneous litigation would duplicate both parties' effort and expense. Therefore, “the probable inefficiency and the potential for the misuse of the limited resources of the judiciary that would occur if this litigation moved forward in Michigan while the case in New Jersey was stayed would be significant.”*Schering*, 2007 WL 1648908, at \*3.

In response, Perrigo argues that Adams' insistence on remaining in New Jersey is in bad faith and is an attempt at improper forum shopping. Perrigo asserts that Adams wants to litigate the case in New Jersey because it would take longer to complete, thereby delaying approval of its generic drug. However, these statements alone—unsupported by evidence—are not sufficient proof of bad faith or forum shopping. As a district court in a factually indistinguishable case stated:

Plaintiff filed the duplicative actions only because of the extraordinary time limit placed on the filing of suits under the Hatch-Waxman Act.

Plaintiff correctly believed that Defendant would challenge personal jurisdiction in Plaintiff's preferred forum and concluded that, should a court in Plaintiff's preferred forum of the District of New Jersey find that jurisdiction was not appropriate there, the timing of the ruling could preclude Plaintiff from filing *any* action under the Act. These circumstances do not demonstrate bad faith or forum shopping on the part of Plaintiff.

*PDL*, 2007 WL 2261386 at \*2. Moreover, given the harsh outcome should the District of New Jersey dismiss the cause of action after the 45 day filing period, the extraordinary circumstances of the case weigh in favor of granting the stay. *Id.*

In its opposition to the motion, Perrigo relies on the case of *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F.Supp.2d 484 (E.D.Va.2005), to argue that the first-to-file rule should not apply when the plaintiff files both actions. While the *Aventis* Court did hold that the first-to-file rule does not apply when the plaintiff files both actions, there is no Sixth Circuit case law mandating such a mechanical limitation. Rather, the doctrine is governed by discretion and equity. *Zide*, 16 F.App'x at 437. In light of the aforementioned factors, equity compels the Court to grant Adams' motion to stay in favor of the first-filed case in New Jersey.

### IV. Conclusion

\*3 The Court will grant Adams' Motion to Stay.

An Order consistent with this Opinion will issue.

W.D.Mich.,2007.

Adams Respiratory Therapeutics, Inc. v. Perrigo Co.

Slip Copy, 2007 WL 4284877 (W.D.Mich.)

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Not Reported in F.Supp.2d  
Not Reported in F.Supp.2d, 2004 WL 225060 (D.Del.)  
(Cite as: **Not Reported in F.Supp.2d**)

Page 1

**C**

Airport Investors Ltd. Partnership, Inc. v. Neatrou  
D.Del.,2004.

Only the Westlaw citation is currently available.

United States District Court,D. Delaware.

AIRPORT INVESTORS LIMITED PARTNER-  
SHIP, INC. and Richard Snyder, General Partner,  
Plaintiff

v.

Douglas J. NEATROUR Dalila E. Neatrou and  
Latino American Media Organization of  
Pennsylvania Defendants.

**No. Civ.A. 03-831 GMS.**

Feb. 3, 2004.

Richard Snyder, pro se, Rehoboth, DE, for Plaintiff.  
[Bruce C. Herron](#), Akin & Herron, P.A., Wilming-  
ton, DE, for Defendants.

#### MEMORANDUM

[SLEET](#), J.

#### I. INTRODUCTION

\*1 On August 25, 2003, the plaintiffs, Richard Snyder ("Snyder") and Airport Investors Limited Partnership, Inc. (collectively, "Airport"), filed the above-captioned contract action against the defendants Douglas Neatrou, Dalila Neatrou and Latino American Media Organization of Pennsylvania ("LAMO") (collectively, the "Neatrous"). Attempting to invoke the court's diversity jurisdiction, Airport's complaint seeks specific performance of an alleged agreement between the parties. On December 29, 2003, Airport filed an amended complaint which included an alternative prayer for breach of contract and a damages remedy in the amount of \$750,000.00.

Presently before the court is the defendants' motion to dismiss this action for lack of subject matter jurisdiction, or, in the alternative, to transfer this action to the United States District Court for the Middle District of Pennsylvania pursuant to 28

[U.S.C. § 1404](#). For the following reasons, the court will grant the Neatrous' motion to transfer.

#### II. BACKGROUND

This case revolves around an alleged contract between Airport and the Neatrous regarding ownership and control of a Pennsylvania radio station. Airport Investors Limited Partnership, Inc. is a Maryland corporation, and its general partner, Snyder, claims to have been a Delaware resident at the time of the filing the present action. Douglas and Dalila Neatrou are residents of Lebanon, Pennsylvania, and LAMO is a Pennsylvania corporation.

On August 7, 2003, three weeks before the filing of the present action, Airport filed a complaint in the United States District Court for the Middle District of Pennsylvania against the same three defendants, alleging a breach of the same contract. In that complaint, Snyder claims to be a citizen of Maryland.

The Neatrous contend that the court should dismiss the instant action for lack of subject matter jurisdiction because Airport's initial complaint prayed only for specific performance of the alleged contract and not for any damages, let alone the minimum \$75,000.00 required for the court to exercise its diversity jurisdiction. Alternatively, the Neatrous move the court to transfer this action to the Middle District of Pennsylvania where Airport first initiated a parallel action to this case. Because Airport subsequently filed an amended complaint as a matter of right, <sup>FN1</sup> the court finds the Neatrous' motion to dismiss the initial complaint moot. With regard to the Neatrous' motion to transfer, however, the court is persuaded that the convenience of the parties and witnesses and interests of justice weigh heavily in favor of transferring the present action to the Middle District of Pennsylvania.

[FN1.Federal Rule of Civil Procedure 15\(a\)](#)



permits a party to file an amended complaint once as a matter of course at any time before a responsive pleading is served. [Fed.R.Civ.P. 15\(a\)](#). Because the Neatrouns' motion to dismiss is not a responsive pleading within the meaning of [Rule 15\(a\)](#), *See, e.g., Kelly v. Del. River Joint Commission*, 187 F.2d 93, 95 (3d Cir.1951), Airport's amended complaint now governs this action.

### III. DISCUSSION

[Section 1404\(a\)](#) provides that “[f]or convenience of [the] parties and witnesses, in the interest of justice,” the court may transfer a civil action “to any other district ... where it might have been brought.” [28 U.S.C. § 1404\(a\)](#). It is the movants' burden to establish the need for transfer, and “the plaintiff's choice of venue [will] not be lightly disturbed.” *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir.1995) (citations omitted).

\*2 When considering a motion to transfer, the court must determine “whether on balance the litigation would more conveniently proceed and the interest of justice be better served by transfer to a different forum.” *Id.* This inquiry requires “a multi-factor balancing test” embracing not only the statutory criteria of convenience of the parties and the witnesses and the interests of justice, but all relevant factors, including “practical considerations that could make the trial easy, expeditious, or inexpensive ... and the local interest in deciding local controversies at home.” *Id.* at 875, 879-80.

Weighing all the factors involved, it is clear that the present case would be most appropriately litigated in the Middle District of Pennsylvania. In this action, a Maryland corporation seeks specific performance of its contract with a Pennsylvania corporation regarding a Pennsylvania radio station. The litigation has virtually no connection to Delaware. No acts relating to the present dispute took place in Delaware, nor do the parties appear to maintain any facilities or documents in Delaware. In addition, both the present case and the case in

the Middle District of Pennsylvania are in the relatively early stages of litigation. Finally, any disparity in court congestion, to the extent there is any, is not so great as to weigh against transfer due to the action currently pending in the Middle District of Pennsylvania.

Snyder's only credible argument in favor of this court retaining jurisdiction over this action is that he is a resident of Delaware.<sup>[FN2](#)</sup> Had Snyder not filed an action against the same three defendants regarding the same contract just three weeks earlier in the Middle District of Pennsylvania, the court might have been persuaded by his argument. Nonetheless, because he chose to file a separate action in the Middle District of Pennsylvania, Snyder inevitably will have to travel to that forum to pursue his claims anyway.

[FN2](#). Interestingly, three weeks before the filing of this action, Snyder claimed to be a resident of Maryland in the complaint he filed in the Middle District of Pennsylvania.

Moreover, although not an issue raised or briefed by either of the parties, the court notes that the “first-filed” rule of this Circuit likely dictates transfer of this case to the Middle District of Pennsylvania. Specifically, “in cases of federal concurrent jurisdiction involving the same parties and issues, the court of first-filing must proceed to decide the matter.” *Zelenkofske Axlerod Consulting, L.L.C. v. Stevenson*, No. 99-CV-3508, 1999 WL 592399, at \*2 (E.D.Pa. Aug. 5, 1999) (citing *EEOC v. University of Pennsylvania*, 850 F.2d 969, 971 (3d Cir.1988)). Unfortunately for Snyder, his choice to file an action in the Middle District of Pennsylvania against the same parties over the same contract before filing the present action has bound him to that venue in the present dispute.

### IV. CONCLUSION

Upon consideration of the [Section 1404](#) criteria and all other relevant factors, the court concludes that the balance of justice and convenience tips



heavily in favor of transfer.

*ORDER*

\*3 For the reasons set forth in the court's memorandum issued contemporaneously herewith, IT IS HEREBY ORDERED that:

1. The Defendants' Motion to Dismiss (D.I.3, paras.1-2) is MOOT;
2. The Defendants' Motion to Transfer (D.I.3, paras.3-5) is GRANTED; and
3. The above-captioned case is TRANSFERRED to the United States District Court for the Middle District of Pennsylvania.

D.Del.,2004.

Airport Investors Ltd. Partnership, Inc. v. Neatrou  
Not Reported in F.Supp.2d, 2004 WL 225060  
(D.Del.)

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(Cite as: Slip Copy)

Page 1

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Alcon Mfg., Ltd. v. Apotex, Inc.  
S.D.Ind.,2007.

Only the Westlaw citation is currently available.

United States District Court,S.D. Indi-  
ana,Indianapolis Division.

ALCON MANUFACTURING, LTD., Alcon  
Laboratories, Inc., and Kyowa Hakko Kogyo Co.  
Ltd., Plaintiffs,  
v.

APOTEX INC. and Apotex Corp., Defendants.  
**No. 1:06-cv-1642-RLY-TAB.**

March 14, 2007.

Adam L. Perlman, Bruce Roger Genderson, Daniel  
P. Shanahan, Jessamyn S. Berniker, Williams &  
Connolly LLP, Washington, DC, Deborah Pollack-  
Milgate, Donald E. Knebel, Paul B. Hunt, Barnes &  
Thornburg LLP, Indianapolis, IN, for Plaintiffs.  
Amy L. Hammer, Craig M. Kuchii, George S. Pav-  
lik, Joseph E. Cwik, Michael A. Krol, Robert B.  
Breisblatt, Sidney Katz, Welsh & Katz, Ltd., Chica-  
go, IL, Abram B. Gregory, Gayle A. Reindl, Som-  
mer Barnard Attorneys, PC, Indianapolis, IN, for  
Defendants.

## ENTRY ON DEFENDANTS' MOTION TO TRANSFER

RICHARD L. YOUNG, United States District  
Judge.

\*1 Defendants Apotex Inc. and Apotex Corp.  
(collectively "Defendants" or "Apotex") move to  
transfer this case to the Southern District of Florida  
pursuant to 28 U.S.C. § 1404(a). For the reasons set  
forth below, the court **DENIES** Defendants' mo-  
tion.

## I. Introduction

Alcon Manufacturing, Ltd. ("Alcon Mfg."), Al-  
con Laboratories, Inc. ("Alcon Labs."), and Kyowa  
Hakko Kogyo Co. Ltd. ("Kyowa") (collectively  
"Plaintiffs") filed the present action on November

15, 2006, alleging patent infringement. The suit  
arose out of Defendants' Abbreviated New Drug  
Application ("ANDA"), which seeks approval for  
Defendants to manufacture and sell a generic ver-  
sion of Plaintiffs' drug Patanol® that is still under  
patent.

Alcon Mfg. is a limited partnership organized  
under the laws of Texas, with its principal place of  
business in Fort Worth, Texas. (Complaint ¶ 2). Al-  
con Labs. is a Delaware corporation with its prin-  
cipal place of business in Fort Worth, Texas. (*Id.* ¶  
3). Kyowa is a Japanese corporation with its prin-  
cipal place of business in Tokyo, Japan. (*Id.* ¶ 4).  
Apotex Inc. ("Apotex Canada") is a Canadian cor-  
poration with its principal place of business in  
Canada. (*Id.* ¶ 5). Apotex Canada developed the  
generic formula of Patanol® and was responsible  
for filing the ANDA. (Answer ¶ 24). Apotex Corp.  
("Apotex USA") is a Delaware corporation with its  
principal place of business in Weston, Florida.  
(Complaint ¶ 6). Apotex USA directs and controls  
the sales and marketing of Apotex products.  
(Defendants' Memorandum in Support at 3). The  
President of Apotex USA also resides in Florida.  
(Declaration of Tammy McIntire ("McIntire Decl.")  
at ¶ 3, Defendants' Memorandum in Support, Ex.  
B). Apotex operates a distribution center in Indi-  
anapolis, Indiana, through which it distributes  
products throughout the United States. (*Id.* ¶ 10).  
The Apotex distribution center employs approxi-  
mately sixteen individuals, none of whom have been  
involved in the ANDA at issue, and no records con-  
cerning the ANDA are stored at the Indianapolis fa-  
cility. (McIntire Decl. at ¶ 4).

Defendants filed the present motion to transfer  
on December 13, 2006, seeking to transfer this case  
to the United States District Court for the Southern  
District of Florida, where Apotex USA resides.

## II. Discussion

Title 28, Section 1404(a) of the United States  
Code states: "For the convenience of parties and



witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.”[28 U.S.C. § 1404\(a\)](#). The parties do not dispute that the Southern District of Indiana and the Southern District of Florida are both proper venues.

The moving party bears the burden to demonstrate that “the transfer will serve the convenience of the parties, the convenience of the witnesses, and the interest of justice.”[State Farm Mut. Auto. Ins. Co. v. Estate of Bussell](#), 939 F.Supp. 646, 651 (S.D.Ind.1996). It is within the discretion of the district court to adjudicate motions to transfer under [§ 1404\(a\)](#) according to an “individualized, case-by-case consideration of convenience and fairness.”[Stewart Org., Inc. v. Ricoh Corp.](#), 487 U.S. 22, 29 (1988) (quoting [Van Dusen v. Barrack](#), 376 U.S. 612, 622 (1964)). Considering the factors set out in [§ 1404\(a\)](#) and the particular circumstances of the case, the moving party must show that the transferee forum is clearly more convenient than the transferor forum. [State Farm](#), 939 F.Supp. at 651.

#### A. Convenience of the Parties

\*2 Defendants argue that the convenience of the parties weighs in favor of transferring the case to the Southern District of Florida because Florida is a more convenient venue for Defendants and no less convenient for Plaintiffs, as the Southern District of Indiana is not Plaintiffs home forum. On the other hand, Plaintiffs argue that Defendants do not meet their burden to show that Florida would be more convenient for the parties and that Plaintiffs' choice of forum in Indiana, although not their home forum, must still be given substantial deference.

Generally, plaintiff's choice of forum is given deference. [State Farm](#), 939 F.Supp. at 651. However, when plaintiff sues outside of his home forum, that choice is given less weight, and the location of defendant's residence becomes more important in determining the convenience of the parties. [Kendall U.S.A., Inc. v. Cent. Printing Co.](#), 666 F.Supp. 1264, 1268 (N.D.Ind.1987). In addition,

in determining the convenience of the parties, the court should consider the parties' respective abilities to bear the expense of trial in a particular forum and the situs of material events giving rise to the suit.[CMG Worldwide, Inc. v. Milton H. Greene Archives, LLC](#), No. 1:05-cv-0415-RLY-TAB, 2005 WL 2175523, at \*4 (S.D.Ind. Sept. 6, 2005).

In this case, Plaintiffs are located in Texas and Japan with no residence in Indiana, while Defendants are primarily located in Canada and Florida with a distribution center in Indiana. Although Plaintiffs filed suit outside of their home forum, thus entitling the location of Defendants' residence in Florida to more consideration, the court finds that transferring the case will not be more convenient for the parties. In this case, neither Indiana nor Florida is an obviously convenient forum. The parties are spread throughout the United States and internationally. In addition, although Plaintiffs' choice of forum may be entitled to *less* deference since they filed outside of their home forum, the court still gives some deference to Plaintiffs' decision to file suit in the Southern District of Indiana.

Further, neither the parties' ability to pay nor the situs of material events weighs in favor of transfer. Both Plaintiffs and Defendants are corporations able to bear the expense of litigation, not individuals that would face significant financial hardship if the litigation remained in Indiana. *See State Farm*, 939 F.Supp. at 651-52 (finding in favor of transfer to the Southern District of Ohio, *inter alia*, because defendants were individuals with minimal assets to pay for a trial in the Southern District of Indiana). Further, the situs of the material events in this case does not weigh in favor of transfer because the facts indicate that the research and development of Defendants' ANDA and the preparation of Plaintiffs' patent on Patanol®, events central to a patent infringement suit, were performed in Canada, Japan, and Texas, not Florida.

\*3 Although Indiana is not Plaintiffs' home forum and Florida is Defendants' home forum, the court finds that such evidence alone is insufficient



to demonstrate that transferring the case to Florida is more convenient for the parties.

### B. Convenience of the Witnesses

Defendants argue that the Southern District of Florida would be more convenient for the witnesses because no witness that would testify about the merits of the patent infringement suit live in Indiana, and Defendants' president, who would likely testify in the suit, resides in Florida. Plaintiff, however, argues that none of the relevant witnesses regarding research and development and expert witnesses regarding the products at issue reside in Florida.

In this case, the development of Defendants' generic product and the preparation of the ANDA took place at Apotex Canada. Apotex USA in Florida controls the sales and marketing of Apotex products. The president of Apotex USA resides in Florida. On the other hand, the research and development of Plaintiffs' patented product, Patanol®, took place in Texas and Japan.

The court finds that Defendants have not met their burden to show that transferring their case to Florida would be more convenient for the witnesses. Defendants can only point to the president of Apotex USA—a collateral witness in the patent infringement suit—who resides in Florida. Defendants note that most of the relevant witnesses will come from Texas, Japan, and Canada; thus, whether the suit remains in Indiana or is transferred to Florida is immaterial because they will have to travel in both situations. However, it is Defendants' burden to demonstrate that the transferring the case is more convenient for the witnesses. Pointing to the residence of Apotex USA's president is insufficient for Defendants to meet their burden to show that transfer is more convenient for *all* witnesses.

### C. Interest of Justice

The interest of justice focuses on public considerations, rather than the private interests of the

parties. See *CMG Worldwide*, 2005 WL 2175523, at \*5. Factors to consider in weighing the interest of the justice include the necessity to apply state law, the conservation of judicial resources, and the likelihood of an earlier trial. *Id.*

Defendants argue that the interest of justice weighs in favor of transfer because Plaintiffs will likely receive a speedier trial in the Southern District of Florida, citing significant statistical data, and Florida has an interest in having local controversies decided in Florida. On the other hand, Plaintiffs argue that the Southern District of Indiana has more experience with patent cases because a major pharmaceutical manufacturer is located in this district and this court has adjudicated similar patent infringement suits. Further, any statistical evidence cited by Defendants does not indicate that a complex patent infringement suit will be adjudicated more quickly in Florida.

\*4 In this case, the interest of justice neither weighs in favor of transferring the case to the Southern District of Florida nor maintaining the case in the Southern District of Indiana. Although Defendants argue that this court has placed great weight on court statistics in transferring cases in the past, citing *CMG Worldwide, Inc. v. Milton H. Greene Archives, LLC*, No. 1:05-cv-0415-RLY-TAB, 2005 WL 2175523, at \*5 (S.D.Ind. Sept. 6, 2005), no statistical evidence was submitted in that case, and the court transferred that case because similar cases had already been consolidated in California. Rather, in this case, the statistical evidence submitted is not persuasive, as the present case involves complex issues and will likely take several years to adjudicate, regardless of the district.

Having local interests resolved locally is also not a factor in this case, as the outcome of a patent infringement case will likely affect consumers nationwide. Patent infringement cases are governed by federal law; thus both the Southern District of Florida and the Southern District of Indiana are competent to govern such suits. Further, both districts have handled patent infringement suits in the



past.

As the convenience of the parties and witnesses and the interest of justice do not weigh in favor of transfer, Defendants have not met their burden to show that transferring the case to the Southern District of Florida is clearly more convenient.

### **III. Conclusion**

For the foregoing reasons, the court **DENIES** Defendants' motion to transfer (Docket # 22) pursuant to [28 U.S.C. § 1404\(a\)](#).

**SO ORDERED.**

S.D.Ind.,2007.

Alcon Mfg., Ltd. v. Apotex, Inc.

Slip Copy, 2007 WL 854026 (S.D.Ind.)

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Slip Copy, 2007 WL 4351019 (N.D.Cal.)  
(Cite as: Slip Copy)

Page 1

Alere Medical, Inc. v. Health Hero Network, Inc.  
N.D.Cal., 2007.

Only the Westlaw citation is currently available.

United States District Court, N.D. California.

ALERE MEDICAL, INC., Plaintiff,

v.

HEALTH HERO NETWORK, INC., Defendant.

No. C 07-05054 CRB.

Dec. 12, 2007.

Patrick T. Weston, Samantha L. Reardon, William Frederick Abrams, Bingham McCutchen LLP, East Palo Alto, CA, for Plaintiff.

Michael A. Ladra, Stefani Elise Shanberg, Wilson, Sonsini, Goodrich & Rosati P.C., Palo Alto, CA, for Defendant.

**ORDER TRANSFERRING VENUE PURSU-  
ANT TO 28 U.S.C. § 1404(a)**

CHARLES R. BREYER, District Judge.

\*1 This case involves allegations of patent infringement by Health Hero Network, Inc. ("Health Hero"), a medical equipment provider, against Alere Medical, Inc. ("Alere"), a health services company. In September of 2007, Health Hero filed a patent infringement claim based on U.S. Patent 7,223,236 ("236 patent") against Alere in the United States District Court, Northern District of Illinois. On October 1, 2007, Alere filed this action for declaratory relief in the Northern District of California, seeking to determine its rights to seven patents owned by Health Hero, none of which are directly at issue in the Illinois action.

Defendant Health Hero Network, Inc. now moves this Court to transfer venue to the Northern District of Illinois pursuant to 28 U.S.C. § 1404(a). Section 1404(a) grants district courts the discretion to transfer any civil action to any other district or division where it might have been brought "[f]or the convenience of parties and witnesses, in the interest of justice." The purpose of this section is to "prevent the waste 'of time, en-

ergy, and money' and 'to protect litigants, witnesses and the public against unnecessary inconvenience and expense.'" *Van Dusen v. Barrack*, 376 U.S. 612, 616, 84 S.Ct. 805, 11 L.Ed.2d 945 (1964) (quoting *Continental Grain Co. v. The Barge FBL-585*, 364 U.S. 19, 26-27, 80 S.Ct. 1470, 4 L.Ed.2d 1540 (1960)). Because interests of justice and judicial economy favor transfer, defendant's motion is GRANTED.

Section § 1404(a) has two requirements: (1) that the district to which the defendants seek to have the action transferred is one in which the action "might have been brought"; and (2) that the transfer be for the convenience of parties and witnesses, and in the interest of justice. Alere does not contest that the Northern District of California would have subject matter of its action pursuant to 28 U.S.C. § 1400(b). Accordingly, the decision to transfer turns on § 1404's second requirement.

With respect to the second factor, the interest of justice is the most important consideration. See *Amazon.com v. Cendant Corp.*, 404 F.Supp.2d 1256, 1261 (W.D.Wash.2005). "Consideration of the interest of justice, which includes judicial economy, may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result." *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1565 (Fed.Cir.1997) (internal quotation omitted). In this case, the interest of justice and considerations of judicial economy strongly favor transfer.

There is a related action in the Northern District of Illinois that shares common technology and products, common parties, and overlapping issues of infringement and validity. Having all the patents before a single judge will obviate the need for duplicative tutorials and evidence, and will facilitate global settlement. Furthermore, Health Hero has submitted evidence demonstrating that the Northern District of Illinois is less congested than this district, which suggests that the dispute will be more



efficiently resolved if transferred.

\*2 On the other side of the scale, Alere persuasively argues that transfer would not necessarily convenience the parties or witnesses. Many of the likely witnesses-including inventors and prosecuting attorneys of the relevant patents-live in California. Moreover, both companies maintain their principal place of business on the West Coast, Health Hero in California and Alere in Nevada. Thus, it is arguable that transferring this case to Illinois will place certain burdens on the parties and likely witnesses.

However, the pertinent question is not simply whether *this* action would be more conveniently litigated in Illinois than California, but whether it would be more convenient to litigate the California and Illinois actions separately or in a coordinated fashion. In the Court's opinion, the interest of justice and judicial economy would be promoted by transferring this case to Illinois to prevent duplicative and unnecessary efforts. Accordingly, Health Hero's motion to transfer is GRANTED.

**IT IS SO ORDERED.**

N.D.Cal.,2007.

Alere Medical, Inc. v. Health Hero Network, Inc.

Slip Copy, 2007 WL 4351019 (N.D.Cal.)

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Slip Copy, 2006 WL 3783477 (D.Del.)  
(Cite as: Slip Copy)

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**C**  
Automotive Technologies Int'l, Inc. v. American  
Honda Motor Co., Inc.  
D.Del., 2006.  
Only the Westlaw citation is currently available.  
United States District Court, D. Delaware.  
AUTOMOTIVE TECHNOLOGIES INT'L, INC.,  
Plaintiff,  
v.  
AMERICAN HONDA MOTOR CO., INC., et al,  
Defendants.  
**Civil Action No. 06-187 GMS.**

Dec. 21, 2006.

Richard K. Herrmann, Morris James LLP, Wilm-  
ington, DE, for Plaintiff.  
Thomas C. Grimm, Benjamin J. Schladweiler, Mor-  
ris, Nichols, Arsht & Tunnell, Wilmington, DE,  
Timothy Q. Delaney, for Defendants.

#### MEMORANDUM

GREGORY M. SLEET, United States District  
Judge.

#### I. INTRODUCTION

\*1 On March 17, 2006, the plaintiff, Automot-  
ive Technologies International, Inc. ("ATI") filed  
the above-captioned action against American  
Honda Motor Company ("Honda"), Elesys North  
America Inc. ("Elesys"), and General Motors Cor-  
poration ("GM"), (collectively the "Defendants"),  
alleging infringement of [United States Patent Nos.](#)  
[5,901,978](#); [6,242,701](#); [6,325,414](#); [6,397,136](#);  
[6,422,595](#); [6,869,100](#); [6,757,602](#); [6,712,387](#);  
[6,942,248](#); [6,950,022](#); and [6,958,451](#), which are  
generally related to technology in automobile seats.  
On May 3, 2006, ATI filed a First Amended Com-  
plaint, adding two additional patents, [U.S. Patent](#)  
[Nos. 6,484,080](#) and [6,850,824](#), and withdrawing  
one of the previously asserted patents, [U.S. Patent](#)  
[No. 6,950,022](#).

On June 16, 2006, ATI filed a separate action,

C.A. No. 06-391, against Hyundai Motor America  
("Hyundai"), BMW of North America LLC  
("BMWNA"), and Kia Motors America Inc.  
("Kia"). Ten of the 12 asserted patents in the  
above-captioned action are asserted in ATI's suit  
against Defendants Hyundai, BMWNA and Kia.  
Presently before the court are motions to transfer  
this action, and the related action, to the Eastern  
District of Michigan, pursuant to [28 U.S.C. §](#)  
[1404\(a\)](#). For the following reasons, the court will  
deny the motion.

#### II. DISCUSSION

Pursuant to [Section 1404\(a\)](#), the court may  
transfer a civil action "for the convenience of  
parties and witnesses, in the interest of justice, ... to  
any other district ... where it might have been  
brought." [28 U.S.C. § 1404\(a\)](#). It is the movant's  
burden to establish the need to transfer, and "the  
plaintiff's choice of venue [will] not be lightly dis-  
turbed." [Truth Hardware corp. v. Ashland Prods.,](#)  
[Inc.](#), No. C.A. 02-1541 GMS, 2003 WL 118005, at  
\* 1 (quoting [Jumara v. State Farm Ins. Co.](#), 55 F.3d  
873, 879 (3d Cir.1995)). In other words, "unless the  
balance of convenience strongly favors a transfer in  
favor of defendant, the plaintiff's choice of forum  
should prevail." [Shutte v. Armco Steel Corp.](#), 431  
F.2d 22, 25 (3d Cir.1970).

When considering a motion to transfer, the  
court must determine "whether on balance the litig-  
ation would more conveniently proceed and the in-  
terest of justice be better served by transfer to a dif-  
ferent forum." [Jumara](#), 55 F.3d at 879. This inquiry  
requires "a multi-factor balancing test," embracing  
not only the statutory criteria of convenience of the  
parties and the witnesses and the interest of justice,  
but all relevant factors, including certain private  
and public interests. *Id.* at 875. These private in-  
terests include the plaintiff's choice of forum; the  
defendant's preference; whether the claim arose  
elsewhere; the convenience of the parties; the con-  
venience of the expected witnesses; and the loca-



tion of books and records, to the extent that they could not be produced in the alternative forum.<sup>FN1</sup> *Id.* at 879. Among the relevant public interests are: “the enforceability of the judgment; practical considerations that could make the trial easy, expeditious, or inexpensive; the relative administrative difficulty in the two fora resulting from court congestion; the local interest in deciding local controversies at home; [and] the public policies of the fora.” *Id.* at 879-80.

FN1. The first three of these private interest factors collapse into other portions of the *Jumara* analysis. Thus, the court will consider them in the context of the entire inquiry only. See *Afymetrix, Inc. v. Synteni, Inc.*, 28 F.Supp.2d 192 (D.Del.1998).

\*2 As an initial matter, the court notes that it will afford less deference to ATI's choice of Delaware as a forum because it is not its “home turf,” or principal place of business. See *Waste Distillation Tech., Inc. v. Pan Am. Res., Inc.*, 775 F.Supp. 759, 764 (D.Del.1991). Nonetheless, the court should not disregard a plaintiff's choice of forum where it has a rational and legitimate reason for choosing the forum. See *Joint Stock Soc'y v. Heublein, Inc.*, 936 F.Supp. 177, 187 (D.Del.1996). With these principles in mind, after consideration of the relevant factors, the court finds that the Defendants have not met their burden of demonstrating that transfer is appropriate.

In the present case, ATI submits the following rationale for suing the Defendants in Delaware: “ATI, and at least one of the Defendants are incorporated in Delaware, all parties are subject to personal jurisdiction in this forum, this forum's docket is noticeably faster to resolution of complex cases than the proposed transferee court and many others, and there was no other forum in which witnesses had a markedly more convenient location than this one.” (D.I. 22 at 2.) The court finds that ATI's explanation is a rational and legitimate reason for choosing to sue the Defendants in Delaware. See *Stratos Lightwave, Inc. v. E20 Communications,*

*Inc.*, No. C.A. 01-309-JJF, 2002 WL 500920, at \* 2 (D.Del. Mar.26, 2002). Further, having received the benefits of Delaware incorporation, a Defendant cannot now complain that another corporation has chosen to sue it here. *See id.*

The court also finds that the location of books and records weighs against granting the Defendants' motion to transfer. The Defendants contend that their books and records necessary for litigation are in Michigan. A court should consider the location of books and records in its analysis. It must only do so, however, to the extent that the files could not be produced in the alternative forum. *Jumara*, 55 F.3d at 879. Here, the Defendants do not suggest that their documents could not be produced in Delaware, especially in this day and age where large-scale “document” productions are reduced to digitized records that parties transfer via electronic media. Accordingly, this factor does not weigh in favor of granting a transfer.

The Defendants also contend that non-party witness convenience weighs in favor of a transfer. The briefs set forth in detail the parties' positions with regard to this factor. Essentially, the Defendants contend that travel to Delaware is less convenient than travel to Michigan for its third-party witnesses. (D.I. 18 at 6-7.) The court is not persuaded by the Defendants' arguments. Further, as this court has previously held, a flight to Delaware is not an onerous task warranting transfer. *Truth Hardware Corp. v. Ashland Prods., Inc.*, No. C.A. 02-1541 GMS, 2003 WL 118005, at \* 2 (D. Del. Jan 13, 2003). The court concludes that the convenience of the witnesses does not favor transfer in this case.

\*3 Additionally, the court finds that the public interest factors do not weigh strongly in favor of transfer to Michigan. First, the court is not persuaded that any disparity in court congestion will be so great as to weigh strongly in favor of a transfer.<sup>FN2</sup> Second, it is well settled that patent rights are not considered state or local matters and do not implicate local interests. *Jones Pharma, Inc. v. KV Pharm. Co.*, No. Civ. A. 03-786 JJF, 2004 WL 323109, at \* 3 (D.Del. Feb.17, 2004). The court,



therefore, finds no strong local interest in litigating in the transferee forum. Third, ATI's pending litigation in Michigan involves different patents. Thus, the court believes that this is not a relevant consideration in favor of transfer. See *Mentor Graphics Corp. v. Quickturn Design Sys., Inc.*, 77 F.Supp.2d 505, 513 (D.Del.1999) (refusing to give "any weight whatsoever" to a mirror image action filed by the defendant).

FN2. Even accepting Defendants' position on the percentage of cases over three years old pending in the Eastern District of Michigan, this district's percentage appears to be lower. Compare (D.I. 22 at 24) with (D.I. 23 at 3, fn. 2).

Finally, the court notes that the circumstances driving the court's decision to transfer in *Alloc, Inc. v. Unilin Decor N.V.*<sup>FN3</sup> are distinguishable from those in the present case. As ATI remarked in its letter of December 12, 2006 (D.I.52), the patents before this court in *Alloc* involved the same patents at issue in the transferee forum. Here, the court is not aware of a single patent in this lawsuit that is asserted in any action in the Eastern District of Michigan. The court agrees with ATI that nothing in the Detroit lawsuits yields any potential savings in judicial economy, given the attenuated connection between those patents and the patents here in suit. Accordingly, the court concludes that public interest factors do not favor transfer in the instant case.

FN3.*Alloc, Inc. v. Unilin Decor N.V., C.A.*  
Nos. 03-253-GMS, 05-587-GMS, 2006  
WL 3050815 (D.Del. Oct.26, 2006).

### **ORDER**

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

The defendants' Motion to Transfer the above-captioned matter to the United States District Court for the Eastern District of Michigan (D.I.17) is DENIED.

D.Del.,2006.

*Automotive Technologies Int'l, Inc. v. American Honda Motor Co., Inc.*  
Slip Copy, 2006 WL 3783477 (D.Del.)

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(Cite as: 2007 WL 1101228 (D.N.J.))

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Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court,

D. New Jersey.

**AVENTIS PHARMA S.A., et al., Plaintiffs,**

**v.**

**SANDOZ INC., Defendant.**

**Civil Action No. 06-3671 (MLC).**

April 10, 2007.

Liza M. Walsh, Agnieszka Antonian, Connell Foley, LLP, Roseland, NJ, for Plaintiffs.

Eric I. Abraham, Hill Wallack, LLP, Princeton, NJ, for Defendant.

#### MEMORANDUM OPINION

COOPER, District Judge.

**\*1** Plaintiffs, Aventis Pharma S.A. and Aventis Pharmaceuticals Inc. (collectively "Aventis"), move to voluntarily dismiss the complaint pursuant to Federal Rule of Civil Procedure ("Rule") 41(a)(2), or in the alternative, to transfer the action to the United States District Court for the Central District of California pursuant to 28 U.S.C. § 1404(a) ("Section 1404"). (Dkt. entry no. 17.) The defendant, Sandoz Inc. ("Sandoz"), cross-moves to dismiss the action and for costs and attorneys fees. (Dkt. entry no. 18.) For the reasons stated herein, the Court will (1) grant the part of the motion seeking to transfer the action to the Central District of California, (2) deny the part of the motion seeking to voluntarily dismiss the complaint pursuant to Rule 41(a)(2), and (3) deny the cross-motion.

#### BACKGROUND

Aventis develops, manufactures, and sells pharmaceutical products. (Compl., at ¶ 2.) Aventis Pharmaceuticals Inc. is incorporated in Delaware and its principal place of business is in Bridgewater, New Jersey. (Id. at ¶ 1.) Aventis Pharma S.A. is a French corporation and its principal place of business is in France. (Id. .) Aventis holds the patent claiming the drug product marketed under the trade name Lovenox ("743 patent"). (Id. at ¶ 8.) The '743 patent will expire on February 14, 2012. (Id. at ¶ A.)

Sandoz develops, manufactures, distributes, and sells generic pharmaceutical products. (Ans., at ¶ 3.) Sandoz is incorporated in Colorado and its principal place of business is in Princeton, New Jersey. (Id.) Sandoz filed with the Federal Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") for the "commercial manufacture, use, and sale of enoxaparin sodium" in certain dosage forms. (Id. at ¶ 10.)

Aventis alleges Sandoz's submission of the ANDA to obtain FDA approval before the expiration of the '743 patent constitutes infringement under 35 U.S.C. § 271(e)(2)(A). (Compl., at ¶ 12.) Aventis seeks a judgment (1) prohibiting the approval of Sandoz's ANDA before the date of expiration of the '743 patent, and (2) enjoining Sandoz from "the commercial manufacture, offer to sell, sale, or importation of its enoxaparin sodium product." (Id. at ¶ A-B.) Sandoz asserts a counterclaim seeking a judgment stating that (1) Sandoz has not infringed the '743 patent, (2) the '743 patent is invalid, and (3) the '743 patent is unenforceable because of Aventis's inequitable conduct. (Ans., at 19.)

Aventis filed complaints raising identical claims of patent infringement against Sandoz in both the District of New Jersey and Central District of California ("California action") on August 4, 2006. (Dkt. entry no. 1; see Central District of California Civ. Dkt. for No. 06-4858, dkt. entry no. 1.) Sandoz filed a motion in California to strike the complaint or in the alternative to transfer the action to New Jersey. (Id., dkt. entry no. 13.) The Judge presiding over the California action denied the motion to transfer. (Id., dkt. entry no. 43.) Sandoz asserted counterclaims in the California action that are identical to the three counterclaims asserted in New Jersey, as well as additional counterclaims. (Id., dkt. entry no. 44.) The Judge presiding over the California action granted Sandoz leave to file a motion for summary judgment on or before April 6, 2007. (Id., dkt. entry no. 49.)

#### DISCUSSION

**\*2** Aventis argues that transfer of the action is appropriate because (1) the matter has already been brought in the Central District of California, and (2) the private and public interests favor transfer. (Pl. Br., at 12.) Sandoz argues that the complaint should instead be dismissed with prejudice and Sandoz should be awarded costs and attorneys fees because (1) Aventis's filing of duplicative litigation and "Judge-Shopping" should not be condoned, and (2) the complaint is redundant and should be stricken under Rule 12(f), and (3) transferring the action "would be a breach of Aventis's promise to the California court to dismiss this Complaint." (Def. Br., at i, 13.)



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## I. Transfer Standard

Section 1404 provides "[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought." 28 U.S.C. § 1404. An action might have been brought in another district, if (1) venue is proper in the transferee district, and (2) the transferee district can exercise jurisdiction over all the parties. *Shutte v. Armco Steel Corp.*, 431 F.2d 22, 24 (3d Cir.1970). In a civil action based on federal question jurisdiction, venue can be laid in a judicial district (1) in which the defendants reside, if all defendants reside in the same state, (2) where a substantial part of the events or omissions giving rise to the claim occurred, or (3) where any defendant may be found if there is no district in which the action otherwise might be brought. 28 U.S.C. § 1391(b). A corporation is considered to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced. 28 U.S.C. § 1391(c).

The movant bears the burden of demonstrating that the alternative forum is more appropriate than the present one. *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir.1995). Courts balance various private and public interests when deciding whether to transfer pursuant to Section 1404. *Jumara*, 55 F.3d at 879. The private interests may include plaintiff's choice of forum, the ease of access to sources of proof, availability of compulsory process over unwilling witnesses, the cost of attendance of willing witnesses, the possibility of a jury view of the premises, the location of books and records to the extent they may be unavailable in one forum, and whether the claim arose elsewhere. See *Gulf Oil v. Gilbert*, 330 U.S. 501, 508 (1946); *Jumara*, 55 F.3d at 879. The public interests may include enforceability of the judgment, practical considerations that could make the trial easy, expeditious or inexpensive, relative administrative difficulty in the two fora resulting from court congestion, local interest in deciding local controversies at home, public policies of the fora, and familiarity of the trial judge with the applicable state law. *Jumara*, 55 F.3d at 879-80. [FN1]

FN1. Plaintiffs may move to transfer venue. See *Ferens v. John Deere Co.*, 494 U.S. 516, 530-31 (1990) (suggesting same).

## II. Transfer as Applied to this Case

\*3 Transfer of this action to the Central District of California is appropriate. As a threshold issue, the Court concludes that Aventis could have brought this matter in the transferee court. See *CIBC World Markets, Inc. v. Deutsch Bank Sec., Inc.*, 309 F.Supp.2d 637, 644

(D.N.J.2004). This action was simultaneously brought in California because the Central District of California is a proper venue, and it can, and already has exercised jurisdiction over Sandoz and denied its motion to transfer the action to New Jersey. (See *dk. entry no. 18, Ex. 5, Tr. of 11-13-06 Motion Hearing.*)

"Although the Court must weigh the factors present in § 1404(a), a plaintiff's choice of a proper forum is a paramount consideration in any determination of a transfer request, and should not be lightly disturbed." *APV N. A., Inc. v. Sig Simonazzi N. A., Inc.*, 295 F.Supp.2d 393, 398 (D.Del.2002). Thus, plaintiffs' choice of forum will prevail even where the factors are evenly balanced or only weigh slightly in favor of transfer, and will only be disturbed where the "balance of convenience of the parties is strongly in favor of the defendant." *Id.* Although plaintiffs here filed complaints in both New Jersey and California, California is their preferred forum. (See *Pl. Br.*, at 12; *dk. entry no. 18, Ex. 5, Tr. of 11-13-06 Motion Hearing.*) The Court finds, for the reasons that follow, that the balance of factors weigh in favor of transfer and therefore will defer to plaintiffs' choice of forum.

The Court concludes that judicial economy mandates transfer of the action to California. "[T]he interests of judicial economy dictate that an action involving the same patents-in-suit and most of the same parties should not proceed simultaneously in two different district courts." *Air Prod. & Chem., Inc. v. MG Nitrogen Servs., Inc.*, 133 F.Supp.2d 354, 357 (D.Del.2001); see also *St. Hill v. Gonzales*, No. 04-4191, 2007 WL 934651, at \*3 (3d Cir. Mar. 29, 2007) (transferring appeal on grounds of "judicial economy" where appeal by same plaintiff in another circuit raised "parallel issues," and other circuit had already accepted review). Both parties admit that the California action is identical to the instant action, and is currently pending and moving forward. (*Pl. Br.*, at 2; *Def. Br.*, at 2.) The Judge overseeing the California action has denied Sandoz's motion to transfer the California action to this Court on the basis of judicial economy. (*Tr. of 11-13-06 Motion Hearing.*) Thus, consideration of judicial economy warrants transfer.

The existence of a separate earlier pending action in the Central District of California involving the same patent at issue in this action also warrants transfer on the basis of judicial economy. The "existence of a prior related action in the transferee district is a strong factor weighing in favor of transfer in the interest of judicial economy." *Zelenkofske Axelrod Consulting, L.L.C. v. Stevenson*, No. 99-3508, 1999 WL 592399, at \*4 (E.D.Pa. Aug. 5, 1999). The Judge assigned to the California action is also assigned to *Aventis v. Amphastar* ("Amphastar action"), EDCV-03-887, which involves the same patent at issue in



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(Cite as: 2007 WL 1101228 (D.N.J.))

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the instant action and the California action. (Declaration of Agnes Antonian ("Antonion Decl."), at Exs. H & I; Pl. Br., at 1.) Trial occurred in the Amphastar action in December of 2006. (See Central District of California Civ. Dkt. for No. 03-887, dkt. entry nos. 893-99.) The California action and this action involve the same patent and defense of invalidity and unenforceability at issue in the Amphastar action, and therefore the existence of this prior related action in California also favors transfer. (Pl. Br., at 3.)

**\*4** The Court finds the private and public interest factors favor transfer. The ongoing litigation of virtually identical claims and counterclaims in California is certainly a "practical consideration[ ] that could make the trial expeditious or inexpensive." *Jumara*, 55 F.3d at 880. The practical considerations weighing in favor of transfer are further indicated by the focus of the parties' arguments to this Court on whether the complaint should be dismissed with or without prejudice, not whether the action should be transferred to California.

Convenience of the witnesses and parties, and the location of documentary evidence, are considerations favoring transfer. Requiring the witnesses, as well as the parties, to appear in two separate actions will not be convenient. (Pl. Br., at 13.) The similarity in issues between the Amphastar action and the current action may also avoid duplication of labor by the parties and both Courts that would arise from failing to transfer this action. (Pl. Reply Br., at 4.) Thus, these convenience factors weigh in favor of transfer.

Any interest New Jersey has in the litigation is outweighed by the interests in judicial economy outlined by the Court. Sandoz admits that it "has no intention of attempting to run around the California court's ruling by moving forward before this Court on the merits of its counterclaims" but nonetheless argues that the complaint should be dismissed with prejudice and its counterclaims stayed while the California action is proceeding. (Def. Br., at 14.) Such an argument flies in the face of the interests in judicial economy advanced by § 1404, and Sandoz's arguments that such a remedy is necessary to "safeguard Sandoz from any future procedural gamesmanship on the part of Aventis" is merely speculative.

The parties' arguments as to whether Aventis filed first in New Jersey are irrelevant to the Court's analysis because the Court has found the balance of all the interests favors transfer in this case. (See Def. Br., at 3; Pl. Reply Br., at 3.) "The first-filed action is preferred ... unless considerations of judicial and litigant economy, and the just and effective disposition of disputes, require otherwise. Thus, the trial court's discretion tempers the

preference for the first-filed suit, when such preference should yield to the forum in which all interests are best served." *Serco Servs. Co. v. Kelley Co.*, 51 F.3d 1037, 1039 (Fed.Cir.1995) (internal cite omitted); see also *Ricoh Co. LTD v. Honeywell, Inc.*, 817 F.Supp. 473, 487 (D.N.J.1993) (departing from first-filed rule because the subsequent forum was more convenient, and the location of witnesses and documents). Here, even if Sandoz was correct in arguing that Aventis filed in New Jersey first or at the same time as California, departure from the first-filed rule is appropriate because the Court's balancing of the interests favors transfer.

There is no indication that Aventis filed the complaint in this district for any improper purpose or motive, or that it engaged in forum-shopping. Any assertions by Sandoz to the contrary are mere conjecture and not supported by the record. The Court finds Aventis's explanation that it filed a virtually identical complaint in New Jersey after filing in California "in case Sandoz contested in personam jurisdiction in California and to preserve its rights to a 30-month stay of FDA approval of Sandoz's application" sufficiently refutes any allegation of judge or forum shopping by Sandoz. Accordingly, transfer, rather than dismissal, will expedite the resolution of Aventis's claims by eliminating the confusion and delays associated with having two identical actions litigated in California and New Jersey. [FN2]

FN2. Dismissal of the complaint without prejudice pursuant to Rule 41(a)(2), requested by plaintiffs, is also not an available remedy because the Court here will not independently adjudicate defendant's counterclaims. See Fed.R.Civ.P. 41(a)(2) ("an action shall not be dismissed against the defendant's objection unless the counterclaim can remain pending for independent adjudication by the court").

#### CONCLUSION

**\*5** The Court, for the reasons stated supra, will grant the part of the motion seeking transfer of the action to the Central District of California. The remaining matters are all denied without prejudice. The Court will issue an appropriate order and judgment.

2007 WL 1101228 (D.N.J.)

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Page 1

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(Cite as: Not Reported in F.Supp.2d)

C

Bristol-Myers Squibb Co. v. Andrx Pharmaceuticals, LLC  
S.D.N.Y., 2003.

United States District Court, S.D. New York.  
BRISTOL-MYERS SQUIBB COMPANY and E.R.  
Squibb & Sons, LLC, Plaintiffs,  
v.  
ANDRX PHARMACEUTICALS, LLC and Andrx  
Pharmaceuticals, Inc., Defendants.  
**No. 03 Civ. 2503(SHS).**

Dec. 5, 2003.

**Background:** Patent holder brought infringement action against competitor.

**Holding:** On competitor's motion to transfer, the District Court, [Stein, J.](#), held that transfer of patent infringement action from Southern District of New York to Southern District of Florida was warranted.

Motion granted.

West Headnotes

#### [1] Federal Courts 170B 1158

170B Federal Courts

170BXIII Concurrent and Conflicting Jurisdiction and Comity as Between Federal Courts

170Bk1152 Transfer and Certification of Cases

170Bk1158 k. Other Particular Cases.  
**Most Cited Cases**

Transfer of patent infringement action from Southern District of New York to Southern District of Florida was warranted, although development of underlying patent took place in New Jersey; identical action was underway in Southern District of Florida, jurisdiction and venue were proper there, designers, developers, and marketers of allegedly infringing patent were employed in Florida, documents could be relocated to Florida without

undue expense, patentee double filed, and it was in interests of judicial economy to avoid duplication of efforts and have lawsuits consolidated.

#### [2] Federal Courts 170B 1153

170B Federal Courts

170BXIII Concurrent and Conflicting Jurisdiction and Comity as Between Federal Courts

170Bk1152 Transfer and Certification of Cases

170Bk1153 k. In General; Transfer Between Divisions. **Most Cited Cases**

A court can transfer an action without resolving whether personal jurisdiction exists over the defendants in the transferor forum. 28 U.S.C.A. § 1404(a).

#### OPINION AND ORDER

STEIN, J.

\*1 Defendants in this patent infringement action, Andrx Pharmaceuticals, LLC and Andrx Pharmaceuticals, Inc., (“Andrx, LLC” and “Andrx, Inc.” or collectively “Andrx”) have moved to dismiss the claims brought against them by Bristol-Myers Squibb Company and E.R. Squibb & Sons, LLC (collectively “Bristol”) for lack of personal jurisdiction pursuant to [Fed.R.Civ.P. 12\(b\)\(2\)](#), or alternatively, for a transfer pursuant to 28 U.S.C. § 1404(a) to the United States District Court for the Southern District of Florida where an identical action is pending before Judge Paul C. Huck. *See Bristol-Myers Squibb Co. et al. v. Andrx Pharmaceuticals, et al.*, No. 03 Civ. 60703 (S.D.Fla.2003); (Trans. of Oral Arg. before Judge Huck, Sept. 5, 2003, p. 7).

#### I. Background

##### A. The Parties

Bristol-Myers Squibb Company is a Delaware corporation with its principal place of business in New York. E.R. Squibb & Sons, LLC is a Delaware



corporation with its principal place of business in New Jersey. Bristol is also the owner of [United States Patent No. 5,006,344](#) (“‘344 patent”) that forms the underlying grounds for this action. (Compl.¶¶ 1, 2, 7).

Defendant Andrx, LLC is a Delaware limited liability company with a principal place of business in Florida. Defendant Andrx, Inc. is a Florida corporation with a principal place of business in Florida. Andrx, Inc. conducts business in New York regularly, but Andrx, LCC does not. Both entities are subsidiaries of Andrx Corporation. (Compl.¶¶ 3, 4, 5, 11-16).

#### B. The Alleged Infringement

Plaintiffs own a patent on a fosinopril formulation which was issued in 1991. (Compl.¶ 7, 8, 10). In 2003, Andrx, Inc. submitted an Abbreviated New Drug Application (“ANDA”) for two products: [fosinopril sodium](#) and [fosinopril sodium with hydrochlorothiazide](#). (*Id.*). Those ANDA applications are the basis for this infringement litigation pursuant to [35 U.S.C. § 271\(e\)\(2\)](#). At some point prior to the litigation, Andrx, Inc. assigned the ANDA applications to Andrx, LLC. (Compl.¶ 11, 12). Andrx, LLC mailed to Bristol, pursuant to [21 CFR § 314.95](#), certain statutorily required “Paragraph IV certification” notices that alert a patent-holder to a challenge or prospective non-infringing use. (*Id.*).

After receiving those notices, Bristol filed this lawsuit in the United States District Court for the Southern District of New York. Subsequently, Bristol also filed an identical complaint in the United States District Court for the Southern District of Florida, and that action is currently underway in Florida. No party contests jurisdiction in the Florida action, although Bristol maintains that it only filed that action to preserve its rights in light of certain misrepresentations by defendants, but not as an exercise of its jurisdictional preference. (See Trans. Oral Arg. before Judge Huck, Sept. 5, 2003, 5:13-18, Def’s Mot. to Dismiss, p. 13).

#### II. Discussion

Plaintiffs have requested that this Court transfer this action pursuant to [28 U.S.C. § 1404\(a\)](#), which allows a district court to transfer an action for “the convenience of parties and witnesses” and “in the interest of justice” to another judicial district where it might have been brought.<sup>FN1</sup> Such a grant is within the discretion of the district court. [In re Cuyahoga Equipment Corp.](#), 980 F.2d 110, 117 (2d. Cir.1992).

FN1. That section reads in its entirety as follows: “For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.”

##### A. Defendants' Burden

\*2 In order to prevail on a motion to transfer pursuant to [section 1404\(a\)](#), the moving party bears the burden of establishing that the convenience of parties and witnesses and the interests of justice will be better served by transfer to another forum. [See Nabisco, Inc. v. Brach's Confections, Inc.](#), No. 00 Civ. 5875, 2000 WL 1677935, at \*3 (S.D.N.Y. Nov.6, 2000); [Toy Biz, Inc. v. Centuri Corp.](#), 990 F.Supp. 328, 330 (S.D.N.Y.1998); [Christina Canada Inc. v. Wior Corp.](#), 702 F.Supp. 461, 464 (S.D.N.Y.1988). “That burden is heavy: ‘unless the balance is strongly in favor of the defendant, the plaintiff’s choice of forum should rarely be disturbed.’” *Id.* at 463 (quoting [Gulf Oil Corp. v. Gilbert](#), 330 U.S. 501, 508, 67 S.Ct. 839, 91 L.Ed. 1055 (1947)). While the plaintiff’s choice of forum is “‘entitled to substantial consideration,’” *Warwick v. General Elec. Co. (In re Warrick)*, 70 F.3d 736, 741 (2d Cir.1995) (quoting [A. Olnick & Sons v. Dempster Bros., Inc.](#), 365 F.2d 439, 444 (2d Cir.1966)), “[t]he emphasis that a court places on plaintiff’s choice of forum diminishes where ... the facts giving rise to the litigation bear little material connection to the chosen forum.” [Fontana v. E.A.R.](#), 849 F.Supp. 212, 215 (S.D.N.Y.1994).

[1] Here, plaintiffs’ selected forum has only a



slight or “tenuous” connection to the operative facts of the litigation, because “plaintiff’s selection of [the] forum has an artificial quality that entitles a court to give it less weight.”*Id. see also Anadigics, Inc. v. Raytheon Co.*, 903 F.Supp. 615, 616 (S.D.N.Y.1995); *Coker v. Bank of America*, 984 F.Supp. 757, 766 (S.D.N.Y.1997) (collecting cases). Bristol-Myer Squibb Company is headquartered in New York, but the research and development of the ‘344 patent took place at E.R. Squibb & Sons, LLC in New Jersey. More importantly, the facts giving rise to this action took place in Florida, as will be fully set forth below. Therefore, the emphasis normally placed on plaintiff’s choice of forum is lessened in this instance.

B. *Transfer Pursuant to section 1404(a): “Convenience” and “Interest of Justice”*

The prerequisite to evaluating the propriety of a transfer is whether there is a transferee forum available with proper jurisdiction and venue. *Alfadda v. Fenn*, 159 F.3d 41, 54 (2d Cir.1998). As noted, an identical action is underway in the Southern District of Florida and all parties agree that jurisdiction and venue are proper there.

Once a finding has been made that the proposed transferee forum has jurisdiction as well as proper venue, a court should assess the “convenience” and “fairness” of a transfer. The court considers factors such as (1) convenience of the witnesses; (2) location of relevant documents and the relative ease of access to sources of proof; (3) locus of operative facts; (4) convenience of the parties; (5) availability of process to compel attendance of unwilling witnesses; (6) relative means of the parties; (7) forum’s familiarity with the governing law; (8) weight accorded a plaintiff’s choice of forum; and (9) trial efficiency and the interests of justice based on the totality of the circumstances. See *Kiss My Face Corp. v. Bunting*, 2003 WL 22244587, at \*1 (S.D.N.Y.2003); *Telebrands Corp. v. Wilton Indus., Inc.*, 983 F.Supp. 471, 477 (S.D.N.Y.1997). An evaluation of the convenience and fairness of granting a transfer should be based

on an “individualized, case-by-case consideration of convenience and fairness.”*In re Cuyahoga Equip. Corp.*, 980 F.2d at 117. The Court shall now turn to a consideration of each of the relevant factors.

1. *The Convenience of the Witnesses*

\*3 “The convenience of the parties and witnesses is generally the most important factor for a court to consider when deciding whether a change of venue is proper.”*Telebrands Corp. v. Wilton Industries, Inc.*, 983 F.Supp. 471, 477 (S.D.N.Y.,1997). “However, the costs and burdens should not merely be shifted from one party to the other.”*Id.*

Bristol has made a showing that a trial in the Southern District of New York would be easier for four of its witnesses, who are located in the New York tri-state area. (Def’s Mem. in Opp. to Mot. to Dismiss, p. 20). For the purposes of this analysis, the Court “dismisses from consideration the convenience of witnesses who are located outside both the current and transferee forums.”*Wechsler v. Macke Int’l Trade, Inc.*, No. 99 Civ. 5725, 1999 WL 1261251, at \*6 (S.D.N.Y.1999). Therefore, the convenience of Bristol’s witness located in California, and of its expert traveling from an unspecified location, is not relevant. Andrx has indicated that “all of the fact witnesses regarding the formulation of the alleged infringing product who may be called to testify are located in Florida.”(Def’s Mot. to Dismiss, p. 16). While Andrx fails to list and name these prospective witnesses, the corporation is located in Florida and a number of employees are located there. Additionally, the witnesses who have already presented testimony in this action, Mr. Whitlock and Mr. Lodin, appear to be employed by Andrx in Florida. Moreover, there is no indication that Bristol’s witnesses will not be able to either travel to Florida or provide testimony by deposition. This factor favors transfer of this action to Florida.

2. *Location of the Documents and Sources of Proof*



Bristol also states that the documents to be produced by all parties in this action are located in the Southern District of New York. (Aff.Park, ¶ 4-7). Andrx has not contended otherwise. The location of documents in New York is “entitled to little weight unless the defendant makes a detailed showing as to the burden it would incur absent transfer.” *Royal Ins. Co. of America v. Tower Records, Inc.*, 2002 WL 31385815, at \*6 (S.D.N.Y. Oct 22, 2002). There has been no such “detailed” showing in this action, and therefore the Court presumes that in this “era of photocopying, fax machines and Federal Express” the documents can be relocated to Florida without undue expense. *Coker*, 984 F.Supp. at 766; see also *Constitution Reinsurance Corp. v. Stonewall Ins. Co.*, 872 F.Supp. 1247, 1251 (S.D.N.Y.1995).

### 3. Locus of Operative Facts

The locus of operative facts is “traditionally an important factor to be considered in deciding where a case should be tried.” *Royal Ins. Co.*, 2002 WL 31385815, at \*3. Andrx is the alleged patent infringer, and that alleged infringement originated at the Florida headquarters of the company. In a patent infringement action, the locus of operative facts is the jurisdiction where the design and development of the infringing patent occurred. *Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp.*, 11 F.Supp.2d 729, 730 (S.D.N.Y.1998). It is also relevant that the designers, developers, and marketers of the allegedly infringing patent are employed in the transferee forum. See *Wechsler*, 1999 WL 1261251, at \*4 (citing *Bionx Implants, Inc. v. Biomet, Inc.*, 1999 WL 342306, at \*4 (S.D.N.Y. May 27, 1999)). It therefore makes little difference that the development of the underlying Bristol patent took place in New Jersey, where the Bristol research facilities are located. The only action taking place in New York was that Andrx mailed certain Paragraph IV notifications to Bristol headquarters in New York. Therefore this factor favors a transfer to Florida; the Southern District of New York has only a tenuous connection to the facts of this litigation.

### 4. Convenience of the Parties

\*4 Not surprisingly, all parties to this action would prefer to try the action in their respective home jurisdictions. The attorneys for all parties appear to be based in New York, but both sets of attorneys are also able to appear in Florida, and have already demonstrated that they are prepared to do so in this matter. Moreover, the convenience of counsel is not relevant to an evaluation of whether to grant a transfer pursuant to section 1404(a). See *Bionx Implants*, 1999 WL 342306, at \*4. The inconvenience to Andrx caused by a suit in New York, though defendants claim it would be great, cannot be overwhelming when Andrx has previously appeared in actions here. See *Aktiebolag v. Andrx Pharmaceuticals, Inc.*, 208 F.R.D. 92 (S.D.N.Y.2002). Bristol alleges that Andrx actually transferred the *Aktiebolag* litigation to the Southern District of New York from the Southern District of Florida, pursuant to section 1404(a). (Def.'s Mem. in Opp. to Mot. to Dismiss, p. 7). Similarly, the inconvenience to Bristol of a suit in the Southern District of Florida could not be overwhelming in light of the fact that it has filed a concurrent action in that forum. Moreover, the parties' convenience is a neutral factor where transfer would only shift the burden from one party to another. *Transatlantic Reinsurance Co. v. Continental Ins. Co.*, No. 03 Civ. 3227, 2003 WL 22743829, at \*6 (S.D.N.Y. Nov 20, 2003). Thus this factor is not decisive one way or the other.

### 5. Ability to Compel Unwilling Witnesses

Neither jurisdiction provides an advantage in the ability of the parties to compel unwilling witnesses. No party has set forth any witnesses who would refuse to appear in either forum; therefore, this factor is also neutral.

### 6. Relative Means of the Parties

No party has indicated that it will not be able to sustain the expenses of litigating in either jurisdiction. This factor cannot be considered absent docu-



mentary proof of any economic hardship that would flow to either party as a result of transferring this action. See *Federman Assocs. v. Paradigm Medical Indus., Inc.*, No. 96 Civ. 8545, 1997 WL 811539, at \*4 (S.D.N.Y. Apr.8, 1997).

#### 7. Forum's Familiarity with Governing Law

The forum's familiarity with the governing law favors neither the Southern District of New York nor the Southern District of Florida. Patent law is federal law and "any district court may handle a patent case with equal skill." *Bionx Implants*, 1999 WL 342306, at \*5; *Recoton Corp. v. Allsop, Inc.*, 999 F.Supp. 574, 578 (S.D.N.Y.1998).

#### 8. Plaintiff's Choice of Forum

"Attention must always be paid ... to the eighth factor - 'the weight accorded the plaintiff's choice of forum' for 'unless the balance is strongly in favor of the defendant, the plaintiff's choice of forum should rarely be disturbed.'" *Amersham Pharmacia Biotech*, 11 F.Supp.2d at 730 (citing *Ford Motor Co. v. Ryan*, 182 F.2d 329, 330 (2d Cir.1950)). However, as set forth above, in this action, the importance of plaintiff's choice of forum is greatly diminished for two reasons.

\*5 First, the forum selected by plaintiff for this action, the Southern District of New York, has only a tenuous connection to the operative facts of the litigation. See e.g. *Fontana v. E.A.R.*, 849 F.Supp. 212, 215 (S.D.N.Y.1994). Second, it is plaintiffs who have filed actions in two forums. Bristol contends that it filed in Florida only to preserve its rights: it feared it would not have proper *in personam* jurisdiction over Andrx, LLC in New York. Only because Bristol believed Andrx, LLC to be a necessary party, it filed the second suit. Therefore, Bristol believes its choice of the Southern District of New York as a forum should still be afforded credit, especially because it has already sought to have the Florida action transferred to the Southern District of New York. (Trans. Oral Arg. before Judge Huck, Sept. 5, 2003, 15:3-6). Nevertheless,

plaintiffs' double-filing does cut against its choice of the Southern District of New York.

#### 9. Trial Efficiency and the Interests of Justice Based on the Totality of the Circumstances

The parties assert that a trial in their respective chosen forums would be more efficient and just. As Bristol points out, this Court has already presided over a trial on the same patent underlying this action and has rendered a decision on that matter. See *Bristol-Myers Squibb Company v. Teva Pharmaceuticals USA, Inc.*, No. 01 Civ. 5572, 2003 WL 22434211 (S.D.N.Y. Oct.27, 2003). To the extent that the parties intend to litigate the same issues here, this factor weighs against a transfer. Bristol believes that the Court's familiarity with "active ingredients" in the tablets, and problems Bristol faced in trying to market a successful tablet free of interaction problems, as well as the Court's exposure to expert testimony, will be relevant. (Plt.'s Mem. In Opp. to Mot. to Dismiss, p. 22). Andrx counters that the issues in this trial will be sufficiently distinct to prevent a duplication of effort in familiarizing a second judge with the facts at issue. (Aff. Blischak ¶ 17-19). The *Teva* action involved a lubricant in the patent, and the issue here relates to other excipients. (*Id.*) As proof of the fact that the issues in the two litigations are perceived by the parties as being different, Andrx quotes Bristol from a discovery dispute in the Southern District of Florida action where Bristol objected to turning over the documents that related to *Bristol-Myers Squibb Company v. Teva Pharmaceuticals USA, Inc.* because Bristol considered those papers to be "irrelevant and not reasonably calculated to lead to admissible evidence." (Def.'s Reply in Supp. of Mot. to Dismiss, p. 9).

Transferring this case to the Southern District of Florida will still serve judicial economy in that the case will cover different issues and this Court's familiarity may not be relevant. The case is also already underway in the Southern District of Florida and there is a scheduled trial date of February 23, 2004. (Def.'s Mot. to Dismiss, Exh. B). Al-



though the action was recently stayed, Judge Huck has told the parties to prepare the case for litigation in Florida, and to continue discovery proceedings. (Trans. Oral Arg. before Judge Huck, Sept. 5, 2003, 15:22-16:18). It is in the interests of judicial economy to avoid a duplication of efforts and to have these two lawsuits consolidated into one action.

\*6 [2] In light of the fact that the motion to transfer this action is being granted, the Court will not consider Andrx's alternative request to dismiss this action for lack of personal jurisdiction. The Court can transfer an action pursuant to [section 1404\(a\)](#) without resolving whether personal jurisdiction exists over the defendants in the transferor forum. See *Fort Knox Music Inc. v. Baptiste*, 257 F.3d 108, 111-12 (2d Cir.2001).

### III. Conclusion

Andrx has made a clear showing that this case should be transferred, both for the convenience of the parties and in the interest of justice. Therefore, for the reasons set forth above, this action is transferred to the Southern District of Florida.

S.D.N.Y.,2003.

Bristol-Myers Squibb Co. v. Andrx Pharmaceuticals, LLC

Not Reported in F.Supp.2d, 2003 WL 22888804 (S.D.N.Y.), 72 U.S.P.Q.2d 1596

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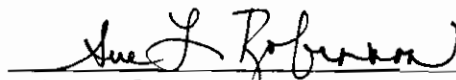
IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CELGENE CORPORATION, NOVARTIS	)	
PHARMACEUTICALS CORPORATION and	)	
NOVARTIS PHARMA AG,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civ. No. 06-741-SLR
	)	
ABRIKA PHARMACEUTICALS, INC. and	)	
ABRIKA PHARMACEUTICALS, LLLP,	)	
	)	
Defendants.	)	

**ORDER**

At Wilmington this 18th day of July, 2007, having considered plaintiffs' motion for a voluntary dismissal without prejudice, and the papers submitted in connection therewith;

IT IS ORDERED that said motion (D.I. 57) is granted, as the court is not persuaded that the facts of this case warrant an exception to the "first filed rule."<sup>1</sup>

  
United States District Judge

---

<sup>1</sup>Although certainly the facts of this case would justify a healthy degree of cynicism regarding plaintiffs' motivation if they oppose an expeditious schedule in the New Jersey case.







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(Cite as: 2007 WL 1456156 (D.N.J.))

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Only the Westlaw citation is currently available.

NOT FOR PUBLICATION

United States District Court,

D. New Jersey.

**CELGENE CORPORATION, Novartis  
Pharmaceuticals Corporation and Novartis Pharma  
AG, Plaintiffs,**  
**v.**  
**ABRIKA PHARMACEUTICALS, INC. and Abrika  
Pharmaceuticals LLLP, Defendants.**  
**Civil Action No. 06-5818(SDW).**

May 17, 2007.

Charles Michael Lizza, William C. Baton, Leboeuf,  
Lamb, Greene & Macrae, LLP, William J.  
O'Shaughnessy, Nicole A. Corona, McCarter & English,  
LLP, Newark, NJ, for Plaintiffs.

Stuart Reiser, Victoria R. Pekerman, Shapiro & Croland,  
PC, Hackensack, NJ, for Defendants.

#### OPINION AND ORDER

WIGENTON, District Judge.

\*1 Before the Court are Defendants Abrika Pharmaceuticals, Inc. ("Abrika Inc.") and Abrika Pharmaceuticals, LLLP's ("Abrika LLLP") (collectively "Defendants") Motion to Dismiss Plaintiffs' Complaint under Federal Rule of Civil Procedure 12(b)(2) and (3), or in the alternative, Transfer to the District of Delaware and Motion to Seal Documents and Plaintiff Celgene Corporation's Motion to Seal Documents. Plaintiffs Novartis Pharmaceuticals Corporation and Novartis Pharma AG (collectively "Plaintiffs") have joined in Celgene Corporation's Opposition. The Court, having considered the parties' submissions and having decided the motions without oral argument pursuant to Fed.R.Civ.P. 78, and for the reasons set forth below, denies Defendants's Motion to Dismiss or Transfer and denies the Motions to Seal Documents.

This Court has jurisdiction pursuant to 28 U.S.C. § § 1331 and 1338(a).

#### I. BACKGROUND

This is a lawsuit for patent infringement arising out of Abrika Inc.'s filing of an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Novartis's RITALIN LA methylphenidate extended-release capsules prior to the expiration of two patents allegedly owned by Celgene Corporation that cover that product and its use. Plaintiffs filed this lawsuit in the Federal District Court, District of New Jersey on December 4, 2006. Two days later, on December 6, 2006 Plaintiffs filed a virtually identical action against the same defendants in the Federal District Court, District of Delaware. Defendants have not contested venue or personal jurisdiction in the Delaware case and have filed responsive pleadings in that matter.

#### II. DISCUSSION

##### Jurisdiction and Venue

Under Federal Rule of Civil Procedure 12(b)(2), a defendant may bring a motion challenging the court's right to exercise personal jurisdiction over them. Once this is done, "plaintiff bears the burden of proving, by a preponderance of the evidence, facts sufficient to establish personal jurisdiction". *Carteret Sav. Bank, F.A. v. Shushan*, 954 F.2d 141, 146 (3d Cir.1992), cert. denied 506 U.S. 817, 113 S.Ct. 61, 121 L.Ed.2d 29 (1992). In doing so, the plaintiff must establish "jurisdictional facts through sworn affidavits or other competent evidence". *Time Share Vacation Club v. Atlantic Resorts Ltd.*, 735 F.2d 61, 66 n. 9 (3d Cir.1984) (citation omitted).

Federal Rule of Civil Procedure 4(e) "authorizes personal jurisdiction over non-resident defendants to the extent permissible under the law of the state where the district court sits." *Mellon Bank (East) PSFS, Nat'l Ass'n v. Farino*, 960 F.2d 1217, 1221 (3d Cir.1992) (citation omitted). Personal jurisdiction over a non-resident defendant is proper where "the defendant's conduct and connection with the forum State are such that he should reasonably anticipate being haled into court there." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297, 100 S.Ct. 559, 62 L.Ed.2d 490 (1980) (citations omitted). Thus, where a "corporation purposefully avails itself of the privilege of conducting activities within the forum State, ... it has clear notice that it is subject to suit there ..." *Id.* New Jersey's "long arm jurisdiction permits the assertion of in personam jurisdiction as far as is constitutionally permissible under the Fourteenth Amendment". *Eaton Corp. v. Maslym Holding Co.*, 929 F.Supp. 792, 796 (D.N.J.1996) (citations omitted).

\*2 To obtain personal jurisdiction, a moving party may assert either general or specific jurisdiction (or both). General jurisdiction is established by demonstrating that



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the defendant has systematic and continuous contacts with the forum state. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 n. 9, 104 S.Ct. 1868, 80 L.Ed.2d 404 (1984). Specific jurisdiction exists when a non-resident defendant purposefully establishes minimum contacts with the forum state and is established where the litigation arises out of or relates to the defendant's forum contacts, provided that the defendant has "certain minimum contacts with [the forum] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Id.* at 414 (citation omitted). Accordingly, before this Court may adjudicate a patent infringement case such as that presented here, specific and/or general jurisdiction over Defendants must be found.

The issue of personal jurisdiction in a patent case is governed by Federal Circuit law regarding due process. *Silent Drive, Inc. v. Strong Indus., Inc.*, 326 F.3d 1194, 1201 (Fed.Cir.2003). The exercise of personal jurisdiction must satisfy the requirements of due process. To so determine, a three step analysis must be applied:

1. Did defendant purposefully direct his activities at the residents in the forum;
2. Does the claim arise out of or relate to those activities; and
3. Is the assertion of personal jurisdiction reasonable and fair.

*Breckenridge Pharmaceuticals Inc. v. Metabolite Labs. Inc.*, 444 F.3d 1356, 1363 (Fed.Cir.2006) (citing *Akro Corp. v. Luker*, 45 F.3d 1541, 1545-46 (Fed.Cir.1995)).

With respect to the third step, the burden is on defendant to show a compelling case that the presence of some other considerations would render jurisdiction unreasonable under the factors set forth by the Supreme Court of the United States in *Burger King*. *Id.* at 1367. These factors are to be considered in determining the fairness of asserting personal jurisdiction over a defendant and consist of:

1. the burden on the defendant;
2. the forum State's interest in adjudicating the dispute;
3. the plaintiff's interest in obtaining convenient and effective relief;
4. the interstate judicial system's interest in obtaining the most efficient; resolution of controversies; and
5. shared interest of the several states in furthering fundamental substantive social policies.

*Id.* In a patent case the crux of the due process inquiry should focus on whether defendant has had contact with the parties in the forum state beyond sending cease and

desist letters or mere attempts to license the patent there. *Id.* at 1366.

With respect to specific jurisdiction, on October 23, 2006 Abrika Inc. notified Celgene, by way of a notification letter, of the ANDA application--as it is required to do pursuant to 21 U.S.C. § 355(j)(2)(B)(i),(iii); 21 C.F.R..314.95(b),(d). The filing of the ANDA triggers a statutory right to sue for patent infringement. However, this alone does not appear to constitute grounds for finding specific jurisdiction as Defendants have taken no step that would constitute infringement such as manufacturing or selling the drug at issue in this state. See *Abbott Labs. v. Mylan Pharmaceuticals Inc.*, 2006 U.S.Dist. Lexis 13782. Abrika Inc. did not perform the development and formulation work in support of the ANDA in New Jersey; the sample of its ANDA product was not manufactured in New Jersey; the clinical studies were not performed in New Jersey; and Abrika Inc.'s personnel and agents did not prepare the ANDA in New Jersey. [FN1]

FN1. This Court will not further discuss the issue of specific jurisdiction since general jurisdiction exists in this matter.

\*3 Nevertheless, while Defendants have no physical presence in New Jersey and the ANDA was not filed or prepared in New Jersey, Defendants's activities within New Jersey constitute continuous and systematic contacts sufficient to warrant general jurisdiction. [FN2] While the ANDA has not yet been approved, and there has been no technical sale of the product in New Jersey, Defendants have entered into contracts with the State of New Jersey. They have also sold drugs and purchased ingredients for their products from companies located in New Jersey. The Defendants' New Jersey related activities include:

FN2. Defendants contend Abrika LLLP and Abrika Inc. are two distinct entities and that this case should be dismissed as to Abrika LLLP because it ceased conducting business in New Jersey prior to this action and on April 1, 2006, Abrika LLLP transferred all its assets and liabilities to Abrika Inc. However, pursuant to New Jersey law, a corporation is imputed with its predecessor's contacts of personal jurisdiction if certain factors are established. *Portfolio Fin. Servicing Co. v. Sharemax.com, Inc.*, 334 F.Supp.2d 620, 625 (D.N.J.2004) (citation omitted). The first three of these factors exist here. (See Savit Decl. at Ex. 3.)

1. In 2006, Abrika Inc. transacted business in approximately 38 states. New Jersey amounted to approximately 8.4% of their annual sales, totaling \$919,106--which was the third highest source of sales for Abrika Inc. in 2006. (Exhibits 7 & 8 to Savit Decl.)



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2. Abrika Inc. entered into two contracts with the State of New Jersey: the August 15, 2003 PAAD Drug Rebate Agreement with the Commissioner of the New Jersey Department of Health and Senior Services whereby Abrika Inc. "a drug manufacturer" was required to enter into and have in effect a Rebate Agreement with the State of New Jersey in order for its drugs to be eligible for state funding when dispersed to NJ PAAD [FN3] beneficiaries (id. at Ex. 23A) and the May 1, 2004 Senior Gold Prescription Discount Program Rebate Agreement (Ex. 24). Both these agreements are effective until June 30, 2007 (Exs. 23B & 25) and both provide for resolution of disputes under New Jersey law, specifically N.J.S.A. 52:14B1 et seq. (Id. at Exs. 23A & 24.)

FN3. The New Jersey program provides drugs and related products to 200,000 low income aged residents.

3. Abrika Inc. also entered into at least three other contracts with the state of New Jersey: WFNJ/GA Drug Rebate Program, N.J. Medicaid Drug Rebate Program and NJ AIDS Drug Distribution Program.

4. Abrika Inc. also purchased goods from companies located in New Jersey. On January 2, 2003 Defendant entered into a five-year Supply Agreement with Sage Chemical Inc. for ingredients to be used in Abrika's products. (Id. at Ex. 27.) Abrika Inc. also entered into a June 1, 2003 Supply Agreement with ISP Technologies. (Id. at Ex. 30.)

5. Abrika LLLP entered into a June 25, 2004 Sales and Marketing Agreement with BiCoastal Pharmaceuticals, a New Jersey corporation (Id. at Ex. 31) and a June 25, 2004 agreement with Well Spring Pharmaceutical Corp. (Id. at Ex. 32).

6. Abrika LLLP contracted with Lawrence T. Freidhoff, who resides in New Jersey, to act inter alia, as an advisor to its CEO. Mr. Freidhoff was paid \$4,000 daily for his services. (Id. at Ex. 27)

7. From 2003 until the present, Abrika has made approximately \$9 million in

purchases from New Jersey companies. (Id. at Ex. 41 & 42, Pl.'s Br. at 24.)

The matter presented to this Court does not involve merely one or two examples of Defendants contacts within New Jersey. The instant case presents systematic and continuous contacts with New Jersey to an extent that warrants a finding of general jurisdiction from at least 2003 to the present. As instructed by the court in *Akro*, supra, the assertion of jurisdiction must be reasonable and

fair. Here, both Abrika Inc. and Abrika LLLP have entered into contracts with the state of New Jersey and companies/individuals in New Jersey. They have also sold and purchased products to and from New Jersey companies and their continued obligation to do is noteworthy. They have certainly availed themselves of the benefits of conducting business here and can not now feign surprise by being sued here by Plaintiffs. Further, Defendants have failed to provide a compelling case that exercising jurisdiction over it would offend principles of fair play and substantial justice. Under *Burger King*, supra, Defendants have not demonstrated an unreasonable burden from litigating this case in New Jersey. New Jersey has an interest in protecting its citizens from patent infringement, and Plaintiffs certainly have an interest in obtaining relief for patent infringement. Neither the interstate judicial system nor the shared interest of the states will be affected by assertion of jurisdiction in this case, because all states are governed by the same body of patent law.

\*4 Federal Rule of Civil Procedure 12(b)(3) allows for dismissal of a complaint for improper venue. In a patent infringement action, proper venue is defined in 28 U.S.C. § § 1400(b) and 1391(c). Venue is proper where the defendant resides, or where it has committed acts of infringement and has a regular and established place of business. 28 U.S.C. § 1400(b). When defendant is a corporation, it is deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced. 28 U.S.C. § 1391. Here, there is personal jurisdiction and venue is therefore proper.

#### Transfer

In the alternative, Defendants contend that the case should be transferred to the District of Delaware pursuant to 28 U.S.C. § 1404(a). A district court may transfer a case "[f]or the convenience of the parties and witnesses, in the interest of justice," provided that the case is transferred to "any other district or division where it might have been brought." 28 U.S.C. § 1404(a). It is not disputed that this case could have been brought in Delaware, as there is a pending action there currently and jurisdiction and venue are uncontested.

"The burden of establishing the need for transfer ... rests with the movant." *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir.1995) (citing *Shuttle v. Armco Steel Corp.*, 431 F.2d 22 (3d Cir.1970)). When deciding motions to transfer, the "plaintiff's choice of venue should not be lightly disturbed," and "the balance must tip strongly in favor of transfer before disturbing the plaintiff's choice." *Market Transition Facility of New Jersey v. Twena*, 941 F.Supp. 462, 467 (D.N.J.1996) (citing *Hardaway Constructors, Inc. v. Conesco Industries, Ltd.*, 583 F.Supp. 617 (D.N.J.1983)).



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The Third Circuit has held that there are both public and private factors to be considered in deciding motions to transfer. *Id.* at 879-880. The private factors to be considered weigh against transfer. Plaintiffs choice of forum is to be given considerable weight in deciding a motion to transfer, and Plaintiffs choice will prevail "unless the party moving for the transfer can convince the court that its alternative forum is not only adequate, but more convenient than the present forum." *Market Transition*, 941 F.Supp. at 467 (citing *Hudson United Bank v. Chase Manhattan Bank*, 832 F.Supp. 881, 888 (D.N.J.1993)) (emphasis added). Defendants argue that Plaintiffs' choice of forum should be given little, if any, weight in the 1404(a) balancing test due to the fact that Plaintiffs also filed suit in Delaware. However, Plaintiffs had legitimate reasons to file a similar, even identical action in Delaware, in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants. Defendants' suggestion that Plaintiffs do not actually have a preference is therefore inaccurate. In addition, Plaintiffs filed in New Jersey first, and did not even serve process on Defendants in Delaware, indicating a clear preference that the case move forward in New Jersey.

**\*5** Other private factors weigh in Plaintiffs' favor also. Given the proximity of this Court and the District of Delaware court, [FN4] there is no reason to believe that transferring the case would be more convenient for the parties or the witnesses, or that transfer would provide easier access to evidence. Although Defendant's choice of forum is to be given some weight in considering a motion to transfer, here Defendants do not even contend that it is more convenient for the case to be in Delaware. Defendants only claim that the case should be in Delaware because that is where they are "incorporated and [have] already submitted to the jurisdiction of the Court." (Def.Br.14.) Neither of these issues are factors to be considered in a 1404(a) motion to transfer.

FN4. It is approximately 110 miles from the District of New Jersey courthouse to the District of Delaware courthouse.

It is unnecessary for the Court to address in detail the public interest factors because, as conceded by Defendants, "there is no appreciable difference between this Court and the Delaware Court regarding many public interest factors." (Def.Br.14.) And while Defendants do suggest that there is a public interest in preventing duplicate litigation (Def.Br.12), and this Court agrees, the cases cited by Defendants predominantly involve the transfer of second filed actions. Here, the first filed action was in New Jersey. The determination of whether the case

should go forward in Delaware or New Jersey is to be made in the framework of a 1404(a) motion to transfer. Because Defendants have not met their burden of showing that transferring the case to Delaware would be more convenient, the motion to transfer is denied.

#### Motion to Seal Documents

Pursuant to Local Civil Rule 5.3(c)(2), any motion to seal documents filed with the Court must include: (a) the nature of the materials or proceedings at issue, (b) the legitimate private or public interests which warrant the relief sought, the clearly defined and serious injury that would result if the relief sought is not granted, and (d) why a less restrictive alternative to the relief sought is not available. The motions to seal filed by both parties have not satisfied the requirements of Local Civil Rule 5.3(c)(2). Neither motion provides legitimate public or private reasons for the documents to be kept from the public, and neither motion sufficiently identifies a clearly defined and serious injury that would result if the motion is not granted, nor do the motions adequately explain why a less restrictive alternative is unavailable. [FN5] Because both parties have failed to satisfy the requirements of Rule 5.3(c)(2), the motions to seal are denied. Both parties will have 20 days to renew their motions and comply with the requirements of the rule. The documents mentioned in the motions will remain temporarily under seal, and if the parties do not renew their motions within 20 days, the documents will be unsealed.

FN5. Both parties only state that there was an agreement to file the documents under seal, and that they are "aware of no less restrictive alternative available."

#### CONCLUSION

For the foregoing reasons, Defendants Motion to Dismiss, or in the Alternative Transfer to the District of Delaware, is Denied and the Motions to Seal Documents are denied, subject to the right of the parties to re-file in compliance with New Jersey Local Rule 5.3(c)(2) within 20 days.

**\*6 SO ORDERED.**

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END OF DOCUMENT







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(Cite as: Not Reported in F.Supp.2d)

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Employers Reinsurance Corp. v. MSK Ins., Ltd.  
D.Kan.,2003.

Only the Westlaw citation is currently available.

United States District Court,D. Kansas.

EMPLOYERS REINSURANCE CORPORATION,

Plaintiff,

v.

MSK INSURANCE, LTD., Defendant.

No. Civ.A.01-2608-CM.

March 31, 2003.

#### MEMORANDUM AND ORDER

MURGUIA, J.

\*1 Plaintiff Employers Reinsurance Corporation (ERC) filed this declaratory action against defendant MSK Insurance, Ltd. (MSK). This matter comes before the court on defendant MSK's Motion to Dismiss or Transfer (Doc. 10).

#### I. Background Facts

From April 1976 to April 2000, ERC reinsured a substantial portion of Memorial Hospital for Cancer & Allied Diseases' (Hospital) first layer excess insurance policies. Defendant MSK is a wholly owned subsidiary of the Hospital and is the captive insurer of New York's Memorial Sloan Kettering Cancer Center (MSKCC), the not-for-profit corporation operating the Hospital. MSK is incorporated and has its principal place of business in the Cayman Islands.

MSK has written the Hospital's excess coverage policies since April 1993. Specifically, the initial Faculative Reinsurance Binder (Binder) that reinsured the initial policy issued by MSK to the Hospital was signed and became effective April 16, 1993, three days after MSK was incorporated. Reinsurance Certificate FCM-51914 eventually replaced the Binder, and every reinsurance certificate issued thereafter was a renewal of the previously is-

sued certificate.

This dispute arises over Reinsurance Certificate FCM-0617297-03-1999 (1999 Reinsurance Certificate), which was issued in April 1999 and expired in April 2001. The Certificate included an unlimited Extending Reporting Period (ERP) option, which entitled MSKCC to convert its coverage upon expiration to an "occurrence" basis,<sup>FN1</sup> covering all losses actually occurring during the policy period, no matter when they were reported. The ERP option was first introduced by the parties into their reinsurance arrangement in the April 1997 reinsurance certificate (1997 Reinsurance Certificate), which was renewed by the 1999 Reinsurance Certificate at issue here. Before April 1997, there was no ERP option included in the reinsurance certificates.

<sup>FN1</sup>. The underlying policy covered professional liability on a "claims made" basis, meaning that the policy covered only loss occurrences actually reported during the policy period.

The ERP option provided that MSKCC could buy such extended coverage by paying 125% of the expiring annual premium. When the 1999 Reinsurance Certificate expired in April 2001, MSKCC notified MSK, who in turn notified ERC, that MSK was invoking the ERP option for its professional liability coverage. MSK requested an invoice for \$1,100,000-125% of the 1999 Reinsurance Certificate's expiring annual premium. ERC representative Richard Pistilli, who was involved in the 1997 reinsurance negotiations, responded that ERC would require a new aggregate retention of \$17 million in order to reinsure the ERP. MSK's insurance agent, Marsh USA, Inc. (Marsh), responded to Mr. Pistilli by letter disputing ERC's right to a new retention.

In May 2001, Marsh, on behalf of MSK, forwarded a check in the amount of \$1,023,000 to ERC's Kansas office, payable "To the order of: Employers Reinsurance Corp, P.O. Box 2991, Over-



land Park, KS 66201.” This amount has been transferred by ERC to a segregated interest bearing account pending resolution of this matter.

In March and May 2002, mediation sessions took place in New York. Before mediation began, in December 2001, ERC filed the instant action. Meanwhile, in March 2002, unaware of this action, MSK filed a lawsuit in the Southern District of New York seeking declaratory relief as well as damages for breach of contract and breach of ERC's duty of good faith and fair dealing. *MSK Ins., Ltd. v. Employers Reinsurance Corp.*, No. 02-CIV-1880 (S.D.N.Y.2002). After the mediation proved futile, each of the parties disclosed their pending suits, and subsequently agreed to exchange service of process simultaneously on May 31, 2002.

\*2 Judge Naomi Reice Buchwald of the Southern District of New York has stayed the New York litigation pending this court's determination of where this dispute should be litigated. Both parties agree that this dispute must be litigated in a single action in one court. MSK argues that this court should dismiss this action for lack of personal jurisdiction or, in the alternative, transfer this action to the Southern District of New York.

## II. Motion to Dismiss for Lack of Personal Jurisdiction

### A. Standards

A plaintiff opposing a motion to dismiss for lack of personal jurisdiction bears the burden of establishing that the exercise of personal jurisdiction over the defendant is proper. *Kuenzle v. HTM Sport-Und Freizeitgerate AG*, 102 F.3d 453, 456 (10<sup>th</sup> Cir.1996). If the motion to dismiss is submitted prior to trial on the basis of affidavits and other written materials, the plaintiff need only make a prima facie showing to avoid dismissal for lack of personal jurisdiction. *Id.* Although the plaintiff will be required to prove the factual basis for jurisdiction by a preponderance of the evidence at trial, on a pretrial motion to dismiss, all factual disputes are resolved in favor of the plaintiff. *Id.* If the plaintiff

makes the required prima facie showing that personal jurisdiction exists, “a defendant must present a compelling case demonstrating ‘that the presence of some other considerations would render jurisdiction unreasonable.’” *OMI Holdings, Inc. v. Royal Ins.*, 149 F.3d 1086, 1091 (10<sup>th</sup> Cir.1998) (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477 (1985)).

In the instant case, the court must determine that the exercise of jurisdiction comports with due process and that an applicable statute potentially confers jurisdiction by authorizing service of process. *Peay v. BellSouth Med. Assistance Plan*, 205 F.3d 1206, 1209 (10<sup>th</sup> Cir.2000). The Kansas long-arm statute is construed liberally to allow jurisdiction to the full extent permitted by due process; therefore, the court proceeds directly to the constitutional analysis. *Federated Rural Elec. Ins. Corp. v. Kootenai Elec. Co-op.*, 17 F.3d 1302, 1305 (10<sup>th</sup> Cir.1994).

Under the due process analysis, the “constitutional touchstone” is “whether the defendant purposely established ‘minimum contacts’ in the forum state.” *Burger King*, 471 U.S. at 474 (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). There must be some act by which the non-resident party purposefully avails itself of the privilege of conducting activities in the forum state. *Hanson v. Denckla*, 357 U.S. 235, 253 (1958). The purposeful availment requirement ensures that a defendant will not be sued in a foreign jurisdiction solely as a result of the unilateral activity of another party. *Burger King*, 471 U.S. at 475.

Consistent with due process, specific jurisdiction may be conferred over a nonresident defendant where the court's exercise of jurisdiction directly arises from a defendant's forum related activities. To determine whether specific jurisdiction is appropriate, the court must first decide whether the defendant has such minimum contacts within the forum state “that he should reasonably anticipate being haled into court there.” *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1979). Second, the court must then consider whether the



exercise of personal jurisdiction offends “traditional notions of fair play and substantial justice.” *Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102, 113 (1987).

## B. Discussion

\*3 To determine whether minimum contacts exist in a contract case, the court must evaluate “prior negotiations and contemplated future consequences, along with the terms of the contract and the parties’ actual course of dealing.” *Burger King*, 471 U.S. at 478-79; *Rainbow Travel Serv., Inc. v. Hilton Hotels Corp.*, 896 F.2d 1233, 1237 (10<sup>th</sup> Cir.1990). A contract with an out-of-state resident is insufficient, standing alone, to establish minimum contacts in that out-of-state forum. *Id.*

MSK argues that the only contacts to be considered in this court’s jurisdictional inquiry are those arising out of the negotiations and execution of the 1997 and 1999 Reinsurance Certificates and that, as a result, this court lacks personal jurisdiction. In support, MSK alleges the following: MSK does not have an office in Kansas, is not registered to do business in Kansas, has no registered agent in Kansas, has never conducted any business in Kansas, and no representative of MSK has ever gone to Kansas to do business with ERC. MSK claims that the 1997 Reinsurance Certificate, which was the first policy to include the ERP option, was negotiated for MSK by its New York-based Vice President-Treasurer Mark Svenningson, and by Patrick Hickey, Sherry Boyar, and Lily Han of Marsh, all of whom live and work in New York. MSK contends that, with the exception of a single conference call, all of MSK’s and Marsh’s communications with ERC regarding this dispute were with Mr. Pistilli of ERC’s New York branch. Further, ERC negotiated and issued the 1997 Reinsurance Certificate through its New York branch and sent representatives to MSKCC’s Manhattan offices for annual claims audits.

In further support, MSK claims that it did not remit its premium payments to ERC’s Kansas office; rather, Marsh sent payments on MSK’s behalf

to Chicago, Illinois. MSK contends that its only routine contacts with ERC in Kansas were quarterly “loss runs” provided by its claims administrator, claims notifications, and litigation updates. Moreover, MSK maintains its files of all significant documents, including copies of policies, loss reports, and relevant correspondence, in New York.

ERC, on the other hand, argues that the court must look to the contacts arising from the origin of MSK’s and ERC’s contractual relationship. ERC points to the language set forth in *Burger King*, which directs the court to evaluate “prior negotiations and contemplated future consequences, along with the terms of the contract and the parties’ actual course of dealing.” *Burger King*, 471 U.S. at 478-79 (emphasis added). Therefore, for purposes of analyzing personal jurisdiction, the court examines the prior negotiations and the parties’ actual course of dealing throughout the duration of MSK and ERC’s contractual relationship.

Prior to the Hospital’s decision to form MSK as a captive insurer, two representatives acting on behalf of the Hospital telephoned Jean Stalcup at ERC’s Kansas office inquiring of ERC’s services as a hospital captive. In response, Paul Longman of ERC’s Kansas office met with Hospital representatives in New York to discuss the formation of a captive insurer.

\*4 As a result of those discussions, MSK was incorporated. Mr. Longman subsequently signed at ERC’s Kansas office the initial Binder that reinsured the Hospital’s initial insurance policy. Reinsurance Certificate FCM-51914 eventually replaced the Binder, and every reinsurance certificate issued thereafter was a renewal of the previously issued certificate. The court believes that the proper jurisdictional inquiry centers upon MSK’s contacts with Kansas from 1993, the time at which the parties signed the original Binder, since every reinsurance certificate issued thereafter was merely a continuation of that Binder.

Foremost, the parties’ relationship began when the Hospital, MSK’s parent company, purposefully



reached into Kansas to contact ERC representatives. Thereafter, from 1994 to 2000, MSK sent letters addressed to Mr. Longman at ERC's Kansas office requesting ERC's assistance in the auditing of MSK's financial statements due to ERC's role in providing MSK's reinsurance. Moreover, MSK admits it routinely provided claims notifications and litigation updates to ERC's Kansas office, and MSK's claims administrator sent quarterly loss reports to ERC's Kansas office. Additionally, pursuant to the terms of the reinsurance certificates, MSK made indemnification requests to ERC's Kansas office. ERC's Kansas office then made indemnification payments by either by issuing a check or by authorizing a wire transfer.

Under these facts, the court finds that MSK engaged in contacts with Kansas such that the exercise of personal jurisdiction is proper. MSK affirmatively reached into Kansas to establish a relationship with ERC and later entered into a contract with ERC, a Kansas resident. That contract, and subsequent reinsurance certificates issued thereafter, required at least partial performance in Kansas. The requirement of partial performance in Kansas is significant to this court. *Marcus Food Co. v. Family Foods of Tallahassee, Inc.*, 729 F.Supp. 753, 757 (D.Kan.1990) (holding that partial performance of contract in Kansas rendered defendant subject to the exercise of personal jurisdiction in Kansas). As such, the court holds that the requirement of minimum contacts was satisfied.

However, even if the court were to accept MSK's argument, that the court should look only to the parties' relationship after the negotiation of the ERP option at issue in this case, the court would still find that MSK engaged in minimum contacts with Kansas. MSK points to the fact that the terms of the 1997 Reinsurance Certificate were negotiated in New York. MSK proffers that ERC created the initial draft of the 1997 Reinsurance Certificate and that it was ERC's draft that was then modified through negotiations in New York between ERC's New York office, MSK representatives, and Marsh. One of the provisions explicitly negotiated in those New York discussions was the ERP option at issue

here.

In response, plaintiff points to other Kansas contacts in which MSK engaged with respect to the 1997 and 1999 Reinsurance Certificates. First, on August 10, 1999, within the 1999 Reinsurance Certificate period, MSK attempted to renegotiate a notice provision such that ERC would be deemed on notice of any claims contained in the quarterly loss runs sent by MSK to ERC's Kansas office. Specifically, Marsh, on behalf of MSK, sent a letter to ERC's Kansas office addressed to Craig Zahnd, ERC Claims Counsel, stating that Marsh hoped ERC would agree to being deemed on notice of such claims. Next, MSK admits it routinely provided notification and litigation updates to ERC's Kansas office. ERC points out that MSK continued to send such notifications of claims to ERC's Kansas office even during the extended reporting period at issue here (after April 16, 2001) and that such claims would be covered under the very ERP option in dispute. Moreover, the letters sent by MSK to ERC's Kansas office requesting ERC's assistance in the auditing of MSK's financial statements continued up until May 30, 2000. Finally, ERC directs the court's attention to MSK's attempted payment for the ERP coverage presently in dispute, specifically a check in the amount of \$1,023,000 forwarded to ERC's Kansas office, payable "To the order of: Employers Reinsurance Corp, P.O. Box 2991, Overland Park, KS 66201."

\*5 The court determines that these transactions, some of which arise directly from the ERP provision at issue here, are sufficient to establish MSK's minimum contacts with the state of Kansas. The court further concludes that the quantity and quality of MSK's contacts are such that the exercise of personal jurisdiction would not offend traditional notions of fair play and substantial justice. Accordingly, the court holds that it has personal jurisdiction over MSK.

### III. Motion to Transfer

As an alternative to its motion to dismiss for lack of personal jurisdiction, MSK moves the court



to transfer this case to the Southern District of New York.

#### A. Standards

Motions to transfer venue are governed by 28 U.S.C. § 1404(a), which provides in pertinent part: “For the convenience of the parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.” 28 U.S.C. § 1404(a).

Section 1404(a) affords the district court broad discretion to adjudicate motions to transfer based upon a case-by-case review of convenience and fairness. *Chrysler Credit Corp. v. Country Chrysler, Inc.*, 928 F.2d 1509, 1516 (10<sup>th</sup> Cir.1991). “The party moving to transfer a case pursuant to § 1404(a) bears the burden of establishing that the existing forum is inconvenient.” *Id.* at 1515. “[U]nless the balance is strong in favor of the movant the plaintiff’s choice of forum should rarely be disturbed.” *Scheidt v. Klein*, 956 F.2d 963, 965 (10<sup>th</sup> Cir.1992) (quoting *William A. Smith Contracting Co. v. Travelers Indem. Co.*, 467 F.2d 662, 664 (10<sup>th</sup> Cir.1972)).

The court must consider the following factors in determining whether to transfer a case:

[T]he plaintiff’s choice of forum; the accessibility of witnesses and other sources of proof, including the availability of compulsory process to insure attendance of witnesses; the cost of making the necessary proof; questions as to the enforceability of a judgment if one is obtained; relative advantages and obstacles to a fair trial; difficulties that may arise from congested dockets; the possibility of the existence of questions arising in the area of conflict of laws; the advantage of having a local court determine questions of local law; and, all other considerations of a practical nature that make a trial easy, expeditious and economical.

*Chrysler Credit Corp.*, 928 F.2d at 1516. The court bears in mind that transfer is not appropriate if the result is merely to shift the inconvenience

from one party to the other. *KCJ Corp. v. Kinetic Concepts, Inc.*, 18 F.Supp.2d 1212, 1214 (D.Kan.1998).

#### B. Discussion

##### a. First-to-File Rule

The present action was filed in this court in December 2001. Eleven weeks later, MSK filed suit in the Southern District of New York, seeking declaratory relief and damages for breach of contract and breach of duty of good faith and fair dealing, and further seeking punitive damages based on ERC’s “reckless, willful and wanton disregard for MSK’s rights.”

\*6 As a general rule, the first suit filed has priority, unless there are circumstances which justify giving priority to a later-filed action. *Venture Corp. v. J.L. Healy Constr. Co.*, Civ. A. No. 88-1351-T, 1988 WL 131354, at \*2 (D.Kan. Nov. 22, 1988). However, the presumption usually afforded the party who files first is not a mechanical rule. Courts have carved out an exception where the first-filed suit constitutes an improper anticipatory filing, or one made under threat of a presumed adversary filing the mirror image of that suit in a different district. *Universal Premium Acceptance Corp. v. Oxford Bank & Trust*, No. 02-2448-KHV, 2002 WL 31898217, at \*2 (D.Kan. Dec. 10, 2002) (citing *Boatmen’s First Nat’l Bank v. KPERS*, 57 F.3d 638, 641 (8<sup>th</sup> Cir.1995) (stating “red flags” that suggest compelling circumstances to disregard first-filed rule include notice that other side was considering filing lawsuit, and fact that first-filed suit was declaratory judgment action)). “A district court may decline to follow the first-to-file rule and dismiss a declaratory judgment action if that action was filed for the purpose of anticipating a trial of the same issues in a court of coordinate jurisdiction.” *Buzas Baseball, Inc. v. Bd. of Regents*, 1999 WL 682883 (10<sup>th</sup> Cir.1999) (citing *Tempco Elec. Heater Corp. v. Omega Eng’g, Inc.*, 819 F.2d 746, 749 (7<sup>th</sup> Cir.1987)).

The present suit is a declaratory judgment ac-



tion. ERC filed this declaratory action in December 2001 as the parties prepared for mediation. ERC did not reveal the suit or serve MSK until after the mediation failed in May 2002. Considering the parties were involved in a contractual dispute, such that mediation was necessary, ERC was effectively on notice that MSK was considering filing a lawsuit asserting affirmative claims for relief in the event mediation proved unsuccessful. The court concludes that the instant declaratory action was filed for the purpose of anticipating a trial of the same issues in another jurisdiction and that ERC's declaratory judgment action is essentially a preemptive strike, rather than a suit for damages or equitable relief. For these reasons, the court declines to apply the first-filed rule.

Moreover, when competing actions are filed within a short time of each other, courts may disregard the first-filed rule. *Universal Premium*, 2002 WL 31898217 at \*2. In this case, ERC filed suit eleven weeks before MSK filed in New York. The court concludes that the two competing lawsuits are close enough in time to convince this court that the first-to-file rule should be disregarded. See *Affinity Memory & Micro v. K & Q Enter.*, 20 F.Supp.2d 948, 954-55 (E.D.Va.1998) (transfer to second court when second action filed only two weeks after first action). Accordingly, given the close proximity of the initiation of the two actions, and the simultaneous service of process in May, the court concludes that first-to-file rule is not applicable in this case.

#### b. Balance of Convenience

\*7 Having determined that the first-filed rule does not apply, the court looks to whether MSK has met its burden of establishing that the existing forum is inconvenient such that transfer of this case to the Southern District of New York is appropriate. The court looks to the factors set forth above that are relevant to this dispute.

**Availability of Non-Party Witnesses.** The court lacks power to compel the appearance of non-party witnesses who reside beyond the 100-mile limit of

this court's subpoena power. *Fed.R.Civ.P. 45(b)(2)*. Thus, the availability of non-party witnesses is important to the court's transfer analysis.

MSK contends that, in offering its proof, it will essentially rely upon three non-party witnesses, Patrick Hickey and Lily Han, current employees of Marsh, and Sherry Boyar, a former employee of Marsh. These three non-party witnesses actively participated in the 1997 and 1999 Reinsurance Certificate negotiations and are, according to MSK, critical to its case. Each of these three non-party witnesses lives and works in New York. These three witnesses would be subject to compulsory process in the Southern District of New York, but could not be compelled to appear before this court. MSK claims that these witnesses will be inconvenienced by having to travel to Kansas to testify and that Ms. Boyer, who no longer works for Marsh, is unlikely to come to Kansas at all.

The court agrees that these non-party witnesses, should they testify at a trial in this court, would be seriously inconvenienced by having to travel to Kansas. Moreover, in addition to the personal inconvenience of these three non-party witnesses, the availability of compulsory process is an important consideration in this transfer analysis. *Cook v. Atchison, Topeka & Santa Fe R.R. Co.*, 816 F.Supp. 667, 669 (D.Kan.1993) ("The availability of process to compel the testimony of witnesses is ... an important factor.") (citation omitted). In *Westhampton Care, Inc. v. Law Co., Inc.*, 896 F.Supp. 1093, 1095 (D.Kan.1995), the court granted a motion to transfer in part because "key witnesses present in New York cannot be compelled to testify in Kansas." See also *Boilermaker-Blacksmith Pension Fund v. Boiler & Mech. Servs., Inc.*, No. 95-2289-JWL, 1995 WL 584500, at \*2 (D.Kan. Sept. 27, 1995) (granting transfer motion in part because key witnesses present in Colorado could not be compelled to testify in Kansas); *Cook*, 816 F.Supp. at 669 ("[T]he defendant faces a real prospect of not being able to exercise the court's compulsory subpoena power.").

ERC argues that MSK would not be prejudiced



by the inability to compel these witnesses to testify in Kansas because MSK can present its testimony by deposition. The court agrees that, in some circumstances, deposition testimony is adequate. However, the central issue in this case is the interpretation of the ERP option contained in the 1997 and 1999 Reinsurance Certificates, and the parties' intent in negotiating that option is key. Thus, MSK's proof will consist primarily of the testimony of these three witnesses, all of whom negotiated the option provision on MSK's behalf. The court concludes that it would be unfair to force MSK to present a significant portion of its case by deposition, *Farr v. Designer Phosphate & Premix Int'l*, 777 F.Supp. 895, 896 (D.Kan.1991), especially in light of the fact that the central issue of the parties' intent may ultimately turn on the credibility of these witnesses.

\*8 In contrast, there are no non-party witnesses who reside in Kansas. Rather, ERC's only non-party witness, Collin Suttie, resides in St. Louis, Missouri. Mr. Suttie is a former ERC employee and has testified by affidavit that Kansas would be a more convenient forum than New York. The court takes note that, in either forum, Mr. Suttie would have to travel.

More significant, the court questions whether Mr. Suttie's testimony would be central to ERC's proof in this case. Mr. Suttie did not personally participate in the 1997 and 1999 Reinsurance Certificate negotiations. Instead, Mr. Suttie's testimony would concern how he "assisted the underwriters" at ERC, his "recommendations of an appropriate aggregate retention," the "assumptions that went into [his] pricing recommendations," and "industry standards and practice." (Suttie Aff. ¶¶ 7-10). Thus, while Mr. Suttie would be more inconvenienced by having to travel to New York rather than Kansas, his testimony is not as central to ERC's case as the testimony of MSK's three non-party witnesses. Thus, ERC would not be as prejudiced by presenting Mr. Suttie's testimony by deposition. The court determines that the factor of the convenience and availability on non-party witnesses weighs strongly in favor of transferring this case to the Southern

District on New York.

Availability of Party Witnesses. MSK contends there will be only two critical party witnesses: Mark Svenningson of MSK and Richard Pistilli of ERC, both of whom work in New York. Mr. Pistilli and Mr. Svenningson, along with the three Marsh employees, actively participated in the negotiation and drafting of the disputed reinsurance contracts. The court concludes that Mr. Svenningson's testimony is critical to MSK's case and that, because he lives and works in New York, his convenience favors New York. ERC argues that there are at least four additional party witnesses, all of whom are employed by ERC in Kansas, and that the convenience of these parties favors Kansas.

ERC contends that these witnesses are knowledgeable about the issues in this case. Specifically, these witnesses' affidavits assert that they have direct knowledge regarding the ERP at issue, negotiations regarding the reinsurance agreement at issue, negotiations regarding the failed attempt of the reinsurance agreement at issue, and pricing of ERPs. The court concludes that, while these witnesses may have knowledge of the transactions involving the agreements at issue, their testimony would not be as critical as the testimony of those who actively participated in the communications and negotiations with MSK representatives. Moreover, these witnesses would likely be available to testify because they are employed by ERC. See *Hill's Pet Prods. v. A.S.U., Inc.*, 808 F.Supp. 774, 778 (D.Kan.1992). In *Hill*, the court ordered a transfer to California even though plaintiff's witnesses resided in Kansas, stating that "[a]lthough [plaintiff's witnesses] may not be subject to compulsory process in California, they would nevertheless be available as witnesses in California as a practical matter because of their employment relationship with [plaintiff], a defendant in the California litigation." *Id.* The court concludes that the convenience of the party witnesses whose testimony is most central to this case (Mr. Svenningson and Mr. Pistilli) favors trying this case in New York.

\*9 Substantive Law: At the outset, the court



notes that, while another state's law may govern the substantive aspects of the parties' contractual dispute, that factor does not, standing alone, require a case to be transferred. See *F.J. Joseph, Inc. v. Lida Adver., Inc.*, 991 F.Supp. 1283, 1285 (D.Kan.1998). However, such a fact may nevertheless be pertinent to the court's analysis of whether the requested transfer should be granted. See *Chrysler*, 928 F.2d at 1516 (in assessing appropriateness of venue transfer, the court is to consider "the advantage of having a local court determine questions of local law").

MSK argues that New York law would govern the Reinsurance Certificate at issue in this case. ERC, on the other hand, contends that the location of contract formation has not been established and that, as a result, ERC is unwilling to concede that New York law applies to this case. However, ERC never suggests that Kansas law would apply.

The court concludes that, in all likelihood, New York law would in fact govern this dispute. As set forth by MSK, the 1999 Reinsurance Certificate was executed by Mr. Pistilli of ERC's New York office, and states on its face that it was issued by ERC's "New York Branch." Moreover, when ERC issued the certificate, it sent the document from ERC's New York office to Marsh in New York, and when Mr. Pistilli signed endorsement no. 1 to that certificate, it was sent from ERC's New York office to MSK's office in Grand Cayman with a letter requesting that it be executed and returned to ERC's New York office. In addition, the ERP provision at issue was mandated by New York Insurance Department Regulations. See 11 N.Y.A.D.C. § 73.4. As such, the court determines that the consideration of having a local court determine questions of local law favors transferring this case to the Southern District of New York.

In sum, the locus of the controversy in this case concerns a Reinsurance Certificate negotiated in New York by an ERC New York representative, and issued by ERC's New York Branch to cover an insured risk in New York. Clearly, the center of gravity of this dispute is in New York. "There is a

local interest in having localized controversies decided at home." *Ferens v. John Deere Co.*, 494 U.S. 516, 530 (1990). The court therefore concludes that the balance is strongly in favor of transferring this case to New York, where it can be consolidated with the nearly identical case pending in the Southern District of New York.

IT IS THEREFORE ORDERED that MSK's Motion to Dismiss or Transfer (Doc. 10) is granted in part and denied in part. This case is hereby transferred to the Southern District of New York.

D.Kan.,2003.  
*Employers Reinsurance Corp. v. MSK Ins., Ltd.*  
Not Reported in F.Supp.2d, 2003 WL 21143105  
(D.Kan.)

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24

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

INPRO II LICENSING, S.A.R.L., )

Plaintiff, )

v. )

Civil Action No. 03-1047 GMS

T-MOBILE USA, INC., RESEARCH IN )  
MOTION LIMITED, and RESEARCH )  
IN MOTION CORPORATION, )

Defendants. )

MEMORANDUM

**I. INTRODUCTION**

On November 18, 2003, the plaintiff InPro II Licensing, S.A.R.L. ("InPro") filed suit against the defendants Research In Motion Limited ("RIM, Ltd."), Research In Motion Corporation ("RIM Corp.") (together the "RIM Defendants") and T-Mobile USA, Inc. ("T-Mobile") (collectively the "Defendants") alleging infringement of its '079 patent. Approximately three weeks before the filing of this action, on October 31, 2003, RIM Ltd. and RIM Corp. filed a declaratory judgment action in the Northern District of Texas against InPro over the same '079 patent asserted in this action and also another patent, the '957 patent (the "Texas Litigation"). Presently before the court is the Defendants' motion to transfer this action to the Northern District of Texas pursuant to the first-filed rule and/or 28 U.S.C. 1404(a). For the following reasons, the court will deny the Defendants' motion.

**II. BACKGROUND**

The plaintiff InPro is a Luxembourg private limited company that has its principle place of business in Luxembourg. Defendant T-Mobile is a Delaware corporation with its corporate offices



located in Bellevue, Washington. Defendant RIM Corp. is also a Delaware corporation with its principle place of business located in Irving, Texas. Defendant RIM Ltd. is a corporation organized under the laws of Ontario, Canada with its principle place of business located in Waterloo, Ontario, Canada.

InPro is the record owner of the '079 patent at issue in this action, which relates to technology for personal digital assistants, or PDAs. Leading up to the filing of the present litigation, InPro had engaged T-Mobile and RIM Ltd. in licensing discussions, contending that their sale of certain products, including those sold under the trade name "Blackberry," may infringe the '079 patent, as well as the '957 patent which is not at issue in this action. The parties exchanged a series of written and oral communications and conducted at least one face-to-face meeting. In the midst of the parties' negotiations, RIM Ltd. and RIM Corp. filed the Texas Litigation. After discovering that RIM Ltd. and RIM Corp. had filed an action in the Northern District of Texas, InPro initiated its own suit against them, as well as T-Mobile, in this court.

## **II. DISCUSSION**

### **A. Transfer Pursuant to 1404(a)**

Section 1404(a) provides that "[f]or convenience of [the] parties and witnesses, in the interest of justice," the court may transfer a civil action "to any other district . . . where it might have been brought." 28 U.S.C. § 1404(a). When considering a motion to transfer, the court must engage in "a multi-factor balancing test" embracing not only the statutory criteria of convenience of the parties and the witnesses and the interests of justice, but all relevant factors, including "practical considerations that could make the trial easy, expeditious, or inexpensive . . . and the local interest in deciding local controversies at home." *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 875, 879-80



(3d Cir. 1995).

Although not specifically enumerated in Section 1404(a), the court should consider certain public and private interests in making its determination. *See id.* at 879. These public interest factors include: (1) enforceability of the judgment; (2) practical considerations that would make the trial easy, expeditious, or inexpensive; (3) relative administrative difficulty in the two fora resulting from court congestion; (4) the local interest in deciding local controversies at home; (5) the public policies of the fora; and (6) the familiarity of the trial judge with the applicable state law in diversity cases. *Id.* Among the private interests a court should consider are: (1) the plaintiff's forum preference as manifested in the original choice; (2) the defendant's preference; (3) whether the claim arose elsewhere; (4) the convenience of the parties as indicated by their relative physical and financial condition; (5) the convenience of witnesses who may be unavailable for trial in one of the fora; and (6) the location of books and records. *Id.* Taking each of these considerations in turn, the *Jumara* factors do not sway the court in favor of either InPro or the Defendants.

#### 1. Public Factors

For public factor (1), the court sees nothing in the parties' papers indicating that a judgment would be any less enforceable in Delaware than in Texas. With regard to factor (3) of the public considerations, the Defendants admit that "both the Northern District of Texas and the District of Delaware are efficient in the administration and resolution of civil matters." (Opening Memorandum of Law in Support of Defendants' Motion to Transfer or Stay at 11). Just as a patent controversy is not unique to Delaware, neither is it unique to Texas, rendering public factor (5) neutral as well. *See Corixa Corp. V. IDEC Pharms. Corp.*, C.A. No. 01-615-GMS, 2002 WL 265094, at \*4 (D. Del. Feb. 25, 2002) ("[T]he court can hardly describe the patents as a local controversy."). Furthermore, the



court will presume that both the District of Delaware and the Northern District of Texas are equally able in applying federal law. Given that this infringement action has been brought under the United States patent laws, the court also sees no difference between the two fora for purposes of public factor (6).

Although at a glance public factors (2) and (4), the Defendants' preference and the local interest in deciding controversies at home, weigh slightly in favor of transfer, the court ultimately concludes that they do not tip the balance in favor of transfer. The Defendants argue that there is more local interest in resolving this matter in Texas because one of the defendants, RIM Corp., which has the exclusive right to grant distributorship in the United States of RIM Ltd.'s accused products, operates its business in Texas. Notably, however, two of the defendants, RIM Corp. and T-Mobile, are incorporated under the laws of Delaware, while none of the defendants are incorporated in Texas. Moreover, short of invoking judicial estoppel, the court finds many of the Defendants' arguments in favor of these factors to be disingenuous considering that RIM Ltd. has brought infringement actions in the District of Delaware on five previous occasions<sup>1</sup> in the last three years.<sup>2</sup> Moreover, in one of those actions, RIM Ltd. successfully opposed a motion to transfer the

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<sup>1</sup>These actions include *Research In Motion v. Glenyare*, Case No. 01-CV-322, filed on May 16, 2001 (patent infringement action before the Honorable Roderick R. McKelvie); *Research In Motion v. Good Technology, Inc.*, Case No. 02-CV-556, filed on June 19, 2002 (patent infringement action before the Honorable Joseph J. Farnan); *Research In Motion v. Good Technology, Inc.*, Case No. 02-CV-566, filed on July 11, 2002 (copyright infringement action before Judge Farnan); *Research In Motion v. Good Technology, Inc.*, Case No. 02-CV-1338, filed on July 29, 2002 (trademark infringement action before Judge Farnan); *Research In Motion v. Handspring, Inc.*, Case No. 02-CV-1480, filed on September 18, 2002 (patent infringement action before Judge Farnan).

<sup>2</sup>In a letter to the court dated March 2, 2004, the Defendants requested leave to file additional briefing on the issue of whether or not the RIM Defendants' previously filed cases in this district are distinguishable from the present action. For the purposes of its findings here, the



case out of this court.<sup>3</sup> These considerations serve to neutralize the little weight the court would have given factors (2) and (4) in the Defendants' favor.

2. Private Factors

Likewise, to the extent factors (2), (4), (5) and (6) of the private considerations may weigh in favor of the Defendants, they are also neutralized by the Defendants' persistent use of this court. More specifically, the Defendants contend the balance of convenience weighs strongly in favor of transferring this case to Texas because InPro has a weak connection to its chosen forum of Delaware. They further claim that there is no reason to believe that there are any relevant witnesses or documents located in Delaware. However, the Defendants do not affirmatively represent that there are any documents or witnesses in Texas either. Given the lack of factual support for their contentions in this regard and the fact, previously noted, that they have filed their own infringement actions in the District of Delaware at least five other times in the recent past, the court is not convinced that retaining this action in the present forum would pose any significant inconvenience to the Defendants.

As for the remaining private considerations, factor (1) clearly weighs against transfer, as InPro has chosen to file its action in the District of Delaware. Private factor (3) is inapposite in that the claim arose neither in the Northern District of Texas nor in the District of Delaware. The alleged infringing products in this action are produced by RIM Ltd., which is incorporated under the laws of the province of Ontario, Canada and has its principle place of business in Waterloo, Ontario,

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court does not consider such additional briefing to be necessary and hereby denies the Defendants' request.

<sup>3</sup>*Research In Motion v. Good Technology, Inc.*, Case No. 02-CV-556, D.I. 129 (March 23, 2003).



Canada. Indeed, there is nothing in the parties' filings indicating that any decision concerning the design or manufacture of the alleged infringing products was made in any jurisdiction outside of Canada.

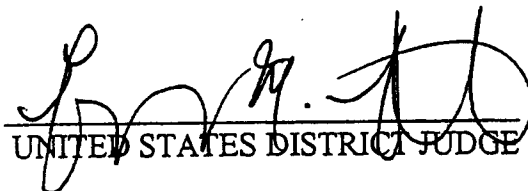
**B. Transfer Pursuant to the First-Filed Rule**

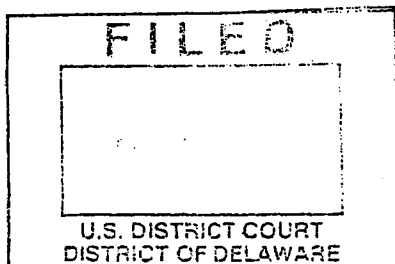
Finally, the court will not entertain the Defendants' first-filed argument as a separate basis for transfer. The tactics employed by the parties on both sides of this action can fairly be described as "hard ball," if not "sharp," practices that essentially negate one another for first-filed rule purposes. That is, as a result of the Defendants' tactics, the court will not give them the benefit of deciding this issue on the first filing rule alone. On the other hand, it will not reward InPro's tactics by granting it an exception to the first-filed rule. Instead, the court will simply add this factor to its *Jumara* analysis and find that it is also neutral for the reasons just stated.

**III. CONCLUSION**

As the court finds the balance of the *Jumara* factors to be largely neutral, it is left with the directive that it is the movants' burden to establish the need for transfer, and "the plaintiff's choice of venue [will] not be lightly disturbed." *Jumara* 55 F.3d at 879 (citations omitted). InPro has filed this litigation in the District of Delaware. In the court's view, the Defendants' have not met their burden of persuasion. Accordingly, the court will deny the Defendants' motion and decline to transfer this action.

Dated: March 5, 2004

  
UNITED STATES DISTRICT JUDGE





25

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

INPRO II LICENSING, S.A.R.L.,

Plaintiff,

v.

Civil Action No. 03-1047 GMS

T-MOBILE USA, INC., RESEARCH IN  
MOTION LIMITED, and RESEARCH  
IN MOTION CORPORATION,

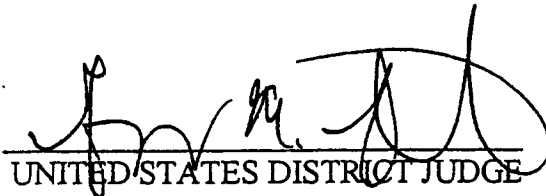
Defendants.

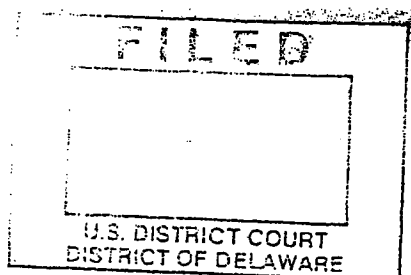
ORDER

For the reasons set forth in the court's memorandum issued contemporaneously herewith,  
IT IS HEREBY ORDERED that:

1. The Defendants' Motion to Transfer or Stay (D.I. 11) is DENIED;
2. The above-captioned action shall proceed to the scheduling conference set for March 9, 2004 before this court.

Dated: March 5, 2004

  
UNITED STATES DISTRICT JUDGE









NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

MEDPOINTE HEALTHCARE INC.,	:	
	:	
	:	
Plaintiff,	:	
	:	Civil Action No. 07-4017 (JAP)
v.	:	
	:	
COBALT PHARMACEUTICALS INC.,	:	
	:	<b>ORDER</b>
	:	
Defendant.	:	
	:	

Presently before the Court is Defendant, Cobalt Pharmaceuticals Inc.’s (“Defendant”) motion to transfer or, in the alternative, stay these proceedings. Plaintiff, Medpointe Healthcare Inc. (“Plaintiff”) opposes the motion.

Both parties operate in the pharmaceutical industry. Plaintiff, a corporation headquartered in New Jersey, owns a patent for a prescription drug, Astelin®, that is used for the treatment of seasonal allergic rhinitis. The named inventor of Astelin® is located in Germany. The Defendant is a business incorporated and located in Canada. The Defendant prepared and compiled an abbreviated new drug application (“ANDA”) in Canada, which it filed with the United States Food and Drug Administration (“FDA”) seeking approval for the marketing of a generic drug to compete with Astelin®.

On August 22, 2007, Plaintiff filed an action alleging patent infringement in the District of New Jersey. Prior to Plaintiff filing this action, Plaintiff inquired as to whether the Defendant would consent to personal jurisdiction in New Jersey, which the Defendant refused to do. The



following day, on August 23, 2007, Plaintiff then filed an identical action in the Northern District of Illinois. The Defendant did not answer the complaint filed in New Jersey, but did answer and file a counterclaim in Illinois. On November 12, 2007, the Defendant filed the present action. The Court heard oral argument on January 25, 2008. Having reviewed the parties' submissions and considered their arguments, the Court now decides the matter.

Section 1404, subsection (a) of Title 28 in the United States Code provides "for the convenience of parties and witnesses, and in the interest of justice, a district court may transfer any civil action to any other district or division or where it might have been brought." The movant carries the burden of establishing the need for a transfer. *See Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir. 1995). In doing so, the movant must show that the alternative forum is not only adequate, but a more appropriate venue than the present forum. *Id.* The Third Circuit in *Jumara* identified a number of factors a court should consider when determining whether a matter should proceed in another forum. Among these factors, a court should consider the parties' preference, where the claim arose, the convenience of the parties and witnesses, the location of books and records, public policy, and other practical considerations. *Id.* at 879-80.

Upon consideration of the various *Jumara* factors articulated in light of the present action, the Court finds that the action is appropriate to be litigated here. The location of Plaintiff's witnesses are in New Jersey. The Plaintiff is headquartered in New Jersey. Furthermore, the Defendant does not have any more connection with Illinois than it does with New Jersey and has not met its burden of demonstrating why the Northern District of Illinois is a more appropriate venue. Moreover, the Defendant represented that it would not contest personal jurisdiction in New Jersey and conceded that venue here is proper. Accordingly, **IT IS**



**ON THIS** 28th day of January, 2008,

**ORDERED** that Defendant's motion to transfer is **DENIED**.

/s/ JOEL A. PISANO  
United States District Judge







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Page 1

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(Cite as: Not Reported in F.Supp.2d)

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MLR, LLC v. U.S. Robotics Corp.

N.D.Ill.,2003.

Only the Westlaw citation is currently available.

United States District Court,N.D. Illinois, Eastern  
Division.

MLR, LLC, Plaintiff,

v.

U.S. ROBOTICS CORPORATION, Toshiba Cor-  
poration, Telefonaktiebolaget LM Ericsson, and  
Samsung Electronics Co., Ltd., Defendants.

No. 02 C 2898.

Feb. 26, 2003.

#### MEMORANDUM OPINION AND ORDER

ST. EVE, J.

\*1 Defendant Nokia Corporation seeks to stay  
and sever this action. For the reasons set forth be-  
low, Defendant's motion is granted in part and  
denied in part.

#### BACKGROUND

On April 24, 2002, MLR filed this case al-  
leging patent infringement against five defendants.  
Nokia was not one of those defendants. MLR and  
Nokia, however, were involved in settlement nego-  
tiations at the time. During the course of these ne-  
gotiations, Nokia requested additional information  
regarding the patents at issue, information "about  
the pending lawsuits and status" and a face to face  
meeting with MLR's attorneys "for a meaningful  
discussion." (See R. 153-1, Pl.'s Br. in Opp. to  
Nokia's Mot. to Sever and Stay, Ex. E.)

Those negotiations apparently reached an im-  
passe because on October 25, 2002, Nokia filed a  
declaratory judgment action in the Northern District  
of Texas seeking non-infringement for 11 patents  
(the "Texas case"). Twelve days later, on Novem-  
ber 6, 2002, MLR filed an amended complaint in  
this case adding Nokia. The amended complaint al-

leges that Nokia infringed six of MLR's patents.  
These six patents are the precise patents that were  
already at issue in MLR's suit against the other de-  
fendants.

#### I. Nokia's Motion to Stay the Action

Nokia now seeks to stay MLR's claims against  
Nokia based on the first to file rule. Nokia argues  
that because it filed the Texas case before it became  
a party to this action, this Court should defer to the  
Texas case's determination of which forum is prop-  
er.

FN1

FN1. MLR has filed a motion to dismiss  
the Texas case on the basis that it lacked  
personal jurisdiction over MLR or, altern-  
atively, in favor of this case. The Texas  
court has not ruled on that motion.

#### A. The Exceptions to the First to File Rule

As the Federal Circuit has explained, when two  
similar actions are filed, there is a "general rule fa-  
voring the forum in which the first suit is  
filed." *Serco Services Co., L.P. v. Kelley Co., Inc.*,  
51 F.3d 1037, 1039 (Fed.Cir.1995) (quoting *Gen-  
entech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937  
(Fed.Cir.1993)). That rule, however, is not abso-  
lute. Indeed, "the trial court's discretion tempers the  
preference for the first-filed suit" where  
"considerations of judicial and litigant economy,  
and the just and effective disposition of disputes,  
require otherwise." *Genetech*, 998 F.2d at 937. See  
also *Colorado River Water Conservation Dist. v.  
United States*, 424 U.S. 800, 817, 96 S.Ct. 1236, 47  
L.Ed.2d 483 (1976) (district courts have the inher-  
ent power to administer their dockets in a manner  
that conserves scarce judicial resources and pro-  
motes the efficient and comprehensive disposition  
of cases). Furthermore, where the first action was  
an anticipatory suit or where forum shopping mo-  
tivated its filing, courts will permit the sub-  
sequently-filed action to proceed. See *Kleinerman  
v. Luxtron Corp.*, 107 F.Supp.2d 122, 124



(D.Mass.2000).

This Court concludes that the present case should be considered an exception to the first to file rule for two reasons. *First*, Nokia's first to file claim is relatively weak. Although MLR actually filed the present action first, Nokia was not named in that initial filing. Presumably, MLR did not name Nokia because the parties were engaged in settlement discussions at the time. It appears that Nokia filed the Texas case only when settlement negotiations broke down so that Nokia might litigate in its chosen forum. As the District of Massachusetts has noted, "it would be inappropriate to reward-and indeed abet-conduct which is inconsistent with the sound policy of promoting extrajudicial dispute resolution, and conservation of judicial resources." *Davox Corp. v. Digital Systems Int'l, Inc.*, 846 F.Supp. 144, 148 (D.Mass.1993).

**\*2** *Second*, the interests of efficiency and economy counsel against invoking the first to file rule here. Nokia cites various cases where the courts have deferred to the first to file rule, but it glosses over the fact that this case involves multiple defendants facing common issues of fact and law. Unlike the cases cited by Nokia, this case and the Texas case do not involve identical parties. Although Nokia and MLR are the only parties in the Texas action, there are six additional defendants in this case. MLR raises the same patents and many of the same claims with these other defendants, and the defendants likely will raise similar defenses to MLR's claims of patent infringement. Because of these other defendants, this case will continue even if Nokia's case were stayed. Discovery in this case is already well underway pursuant to the Court's order. It would be terribly inefficient and a waste of judicial resources to stay Nokia's case now and force them to duplicate later much of the discovery already being conducted by the other defendants in this case.

#### B. Jurisdiction to Deny the Stay

Nokia argues that the Texas court should make the determination of which case should proceed.

Given the posture of this case, however, this Court has the authority to deny the motion to stay. "Federal district courts have the inherent power to administer their docket so as to conserve scarce judicial resources." *Trippe Mfg. Co. v. American Power Conversion Corp.*, 46 F.3d 624, 628 (7<sup>th</sup> Cir.1995).

#### II. Nokia's Motion to Sever

Nokia also seeks to sever MLR's claims against it on the basis of misjoinder, jury confusion and prejudice. Nokia argues that it is misjoined pursuant to [Federal Rule of Civil Procedure 20\(a\)](#). Rule 20(a) provides that a plaintiff may join multiple defendants in a single action "if there is asserted against them jointly, severally, or in the alternative, any right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all defendants will arise in the action." Thus, there is a two-part test to determine whether Nokia is properly joined under Rule 20(a): (1) the claims asserted against the defendants must arise out of the same transaction or occurrence, and (2) there must be a common question of law or fact. Although the second element is clearly satisfied, the first is not.

The defendants are companies with offices all over the world. MLR alleges that each company has infringed certain MLR patents used in connection with cellular telephone products by manufacturing, using and selling their respective products in the United States. MLR does not allege, however, that the defendants' products are related. Accordingly, MLR has not met the common transaction or occurrence element under Rule 20(a). See, e.g., *Androphy v. Smith & Nephew, Inc.*, 31 F.Supp.2d 620, 623 (N.D.Ill.1998) (severing claims against multiple defendants where defendants are "separate companies that independently design, manufacture and sell different products in competition with each other").

**\*3** MLR argues that Rule 20(a) is satisfied because the *defenses* asserted by Defendants arise out of the same transaction or occurrence. Rule 20(a),



however, requires that a *claim* asserted against the Defendants arise out of the same transaction or occurrence. Thus, the fact that the defendants' defenses may arise out of the same transaction or occurrence is not sufficient for joinder under Rule 20(a).

MLR also argues that Nokia is properly joined because the courts routinely consolidate cases for pretrial purposes in order to avoid duplication of effort and to promote efficiency. In *Magnavox Co. v. APF Electronics, Inc.*, for example, the court concluded that a defendant was misjoined but nonetheless refused to sever the defendant because it "would deter the efficient and orderly pursuit of this litigation."<sup>496</sup> F.Supp. 29, 34 (N.D.Ill.1980). The *Magnavox* case, however, does not stand for the proposition that efficiency alone is adequate basis for joinder. At most, that case suggests that, even if not properly joined, cases involving different defendants may be ripe for consolidation. This Court could not find any authority that would permit it to keep a misjoined defendant in the suit simply to vindicate the interests of judicial economy and efficiency. Accordingly, the Court finds that Nokia is not properly joined here.

Nonetheless, the Court construes MLR's argument based on the *Magnavox* case as a request in the alternative for consolidation under Federal Rule of Civil Procedure 42(a). Given the overlapping common questions of law and fact, this Court agrees that MLR's case against Nokia is ripe for consolidation with the case against the other defendants under Rule 42(a).<sup>FN2</sup>

<sup>FN2</sup>. Nokia also argues that it should be severed because of the discovery schedule adopted by the Court on October 3, 2002. Nokia contends that discovery is well underway with respect to the defendants (which were sued by MLR in April of 2002) and that imposing the current schedule on Nokia (which was not sued until November of 2002) would be unduly prejudicial. While Nokia's argument may have some merit, the Court notes that it may be

addressed in a motion to extend the current discovery schedule.

#### CONCLUSION

Nokia's motion to stay is denied. Nokia's motion to sever, however, is granted. MLR's claims against Nokia will be consolidated for pretrial purposes with this case.

N.D.Ill.,2003.

MLR, LLC v. U.S. Robotics Corp.

Not Reported in F.Supp.2d, 2003 WL 685504 (N.D.Ill.)

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PDL Biopharma, Inc. v. Sun Pharmaceutical Industries, Ltd.

E.D.Mich., 2007.

Only the Westlaw citation is currently available.

United States District Court, E.D.

Michigan, Southern Division.

PDL BIOPHARMA, INC., Plaintiff,

v.

SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Defendant.

**Civil Case No. 07-11709.**

Aug. 6, 2007.

Robert L. Kelly, Dickinson Wright, Bloomfield Hills, MI, [David J. Tsai](#), Townsend, Townsend, San Francisco, CA, [Madison C. Jellins](#), Townsend and Townsend, Palo Alto, CA, for Plaintiff.

[Michael K. Nutter](#), Winston and Strawn, Chicago, IL, [Moheeb H. Murray](#), [Raymond M. Kethledge](#), Bush, Seyferth, Troy, MI, for Defendant.

***ORDER GRANTING PLAINTIFF'S MOTION  
TO STAY THE PROCEEDINGS***

[PAUL V. GADOLA](#), United States District Judge.

\*1 Before the Court is Plaintiff's motion to stay the proceedings in this case pending the outcome of identical litigation in the District of New Jersey. For the reasons stated below, Plaintiff's motion will be granted.

**I. Background**

This is a patent infringement action. On March 5, 2007, Plaintiff PDL BioPharma, Inc. ("PDL") received a letter from Defendant Sun Pharmaceutical Industries ("Sun") indicating that Sun had filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration to produce a generic version of PDL's patented drug product, CARDENE® I.V. Under the Hatch-Waxman Act of 1984, once the owner of a patented drug receives notice from the FDA of an application to produce a

generic version of the drug, the owner must file an action within 45 days in order to obtain a 30-month stay of approval of the production of the generic drug. <sup>FN1</sup>

**FN1.** The respective stay, if granted, commences from the date of notice of filing rather than the date of commencement of the litigation.

In the present case, Plaintiff PDL filed two actions in federal court following notice of Sun's ANDA. The first was filed in the District of New Jersey on April 16, 2007. Due to its presumption that Sun would challenge jurisdiction in New Jersey, PDL filed a second suit in this Court on the following day, April 17, 2007, as a protective measure, recognizing that Sun has previously consented to personal jurisdiction in this Court. PDL claims that it filed two suits only to protect itself should it lose the jurisdictional challenge in New Jersey after the 45 day filing window had closed.

This court has now been notified that, although Sun initially contested personal jurisdiction in the District of New Jersey, Sun has now consented to personal jurisdiction in that district. However, Sun has filed a motion in the District of New Jersey to transfer venue in that case to the Eastern District of Michigan.

Now, before this Court is Plaintiff's motion to stay the proceedings in this district pending the outcome of the New Jersey action.

**II. Legal Standard**

The first-to-file rule is a well established doctrine that encourages comity among federal courts of equal rank. *Zide Sport Shop of Ohio, Inc. v. Ed Tobergte Assoc., Inc.*, 16 F. App'x 433, 437 (6th Cir. 2001). The rule generally states, "[W]hen actions involving nearly identical parties and issues have been filed in two different [federal] district courts, 'the court in which the first suit was filed



should generally proceed to judgment.’ “ *Id.* (quoting *In re Burley*, 738 F.2d 981, 988 (9th Cir.1984)). See also *Smith v. McIver*, 9 Wheat. 532, 22 U.S. 532, 535, 6 L.Ed. 152 (1824) (“[i]n all cases of concurrent jurisdiction, the Court which first has possession of the subject must decide it.”). However, the first-to-file rule is not a blanket rule and the district courts may dispense with it as equity so requires. *Zide Sport Shop*, 16 F. App’x at 437. When evaluating whether to apply the rule, district courts are to consider several factors that weigh against adherence. “Factors that weigh against application of the [first-to-file] rule include ‘extraordinary circumstances, inequitable conduct, bad faith, anticipatory suits, and forum shopping,’ “ *Nartron Corp. v. Quantum Research Group, Ltd.*, 473 F.Supp.2d 790, 795 (E.D.Mich.2007) (quoting *Zide*, 16 Fed. App’x. at 437), as well as significant policy considerations. See *AmSouth Bank v. Dale*, 386 F.3d 763, 791 n. 8 (6th Cir.2004). A party seeking a stay in proceedings must establish “a clear case of hardship or inequity” before a court determines that a stay is proper. *Landis v. N. Am. Co.*, 299 U.S. 248, 255, 57 S.Ct. 163, 81 L.Ed. 153 (1936).

### III. Analysis

\*2 In the present case, the Court finds that the application of the first-to-file rule is appropriate. Presently there are two identical actions pending in two separate districts. Going forward with both actions simultaneously would waste scarce judicial resources <sup>FN2</sup>, not to mention the resources of the parties involved. Furthermore, proceeding with both actions would present the distinct possibility of conflicting rulings or judgements. Avoiding such a result is the very reason the Court follows the principle of comity. See *Church of Scientology of Cal. v. U.S. Dep’t of Army*, 611 F.2d 738, 750 (9th Cir.1979) (“The purpose of the comity principle is of paramount importance. The doctrine is designed to avoid placing an unnecessary burden on the federal judiciary, and to avoid the embarrassment of conflicting judgments....”); *Pacesetter Sys., Inc. v. Medtronic, Inc.*, 678 F.2d 93, 96 (9th Cir.1982) (

“[P]ermitting multiple litigation of these identical claims could serve no purpose of judicial administration, and the risk of conflicting determinations ... [is] clear.”).

FN2. As evidence of the significant judicial resources that could be expended by allowing parallel litigation to proceed, the Court need only consider the multiplicative filings submitted to this Court pending the outcome of the motion to stay. Following each and every event in the New Jersey litigation, the parties filed briefs in this Court, updating the Court as to status of the New Jersey litigation and arguing how those events may affect the motion to stay. The Court could only expect the numbers of such filings to increase were this Court to allow the two cases to proceed simultaneously on the merits.

Considering Defendant's arguments in this case, the Court finds them unavailing. There is no question that Plaintiff filed two identical actions. However, there is no evidence of bad faith or forum shopping. See *Nartron Corp.*, 473 F.Supp.2d at 795. Plaintiff filed the duplicative actions only because of the extraordinary time limit placed on the filing of suits under the Hatch-Waxman Act. Plaintiff correctly believed that Defendant would challenge personal jurisdiction in Plaintiff's preferred forum and concluded that, should a court in Plaintiff's preferred forum of the District of New Jersey find that jurisdiction was not appropriate there, the timing of the ruling could preclude Plaintiff from filing *any* action under the Act. These circumstances do not demonstrate bad faith or forum shopping on the part of Plaintiff. See *id.* Furthermore, given the strict deadline and the potentially harsh outcome should Plaintiff's preferred forum dismiss the cause of action after the deadline, a consideration of the “extraordinary circumstances” of the case, see *id.*, weighs in favor of the stay. Finally, Defendant's arguments regarding the prejudice it will face due to the delay in the New Jersey court are unpersuasive to *this* Court. Any concern about undue delay in New Jersey,



whether on the part of the Court or of any party participating in that litigation, are best addressed by *that* court. Requiring two courts to adjudicate identical suits will do nothing to further judicial efficiency or reduce delays in this case or any others.

#### IV. Conclusion

Although the Court cannot condone the routine use of the filing of “protective” lawsuits, given the unusual nature of ANDA claims and absent any guidance in the statute or case law regarding the handling of such “protective” suits, the Court finds that Plaintiff has satisfied its burden for a stay. Allowing two identical suits to proceed in a parallel manner would clearly be contrary to the principles of comity and would waste scarce judicial resources. Accordingly, the Court finds that the first-to-file rule should be applied in this case. The Court will issue a stay of this case pending further action in the parallel New Jersey litigation.

**\*3** For the foregoing reasons, **IT IS HEREBY ORDERED** that Plaintiff's motion to stay this cause of action [docket entry # 11] is **GRANTED**; this cause of action is **STAYED** pending further notice by the Court.

**IT IS FURTHER ORDERED** that, the Clerk of the Court administratively **CLOSE** this case pending further notice by the Court.

**IT IS FURTHER ORDERED** that, should the parallel New Jersey action proceed to a decision on the merits or otherwise reach resolution, the parties shall **NOTIFY** this Court within **TEN (10) DAYS**.

**SO ORDERED.**

E.D.Mich.,2007.  
PDL Biopharma, Inc. v. Sun Pharmaceutical Industries, Ltd.  
Slip Copy, 2007 WL 2261386 (E.D.Mich.)

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(Cite as: 2006 WL 3755452 (D.Del.))

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**H**

Only the Westlaw citation is currently available.

United States District Court,

D. Delaware.

**PERNOD RICARD USA, LLC, Plaintiff,**  
**v.**  
**BACARDI U.S.A., INC., Defendant.**  
**No. CIV 06-505-SLR.**

Dec. 19, 2006.

Rodger Dallery Smith, II, Morris, Nichols, Arsht & Tunnell, Wilmington, DE, for Plaintiff.

Anne Shea Gaza, Richards, Layton & Finger, Wilmington, DE, for Defendant.

#### MEMORANDUM ORDER

ROBINSON, J.

\*1 At Wilmington this 19th day of December, 2006, having considered defendant's motion to transfer and the papers submitted in connection therewith;

IT IS ORDERED that said motion to transfer (D.I.6) is denied, for the reasons that follow:

1. Introduction. On August 15, 2006, plaintiff Pernod Ricard USA, LLC ("Pernod") filed this action alleging defendant Bacardi USA, Inc. ("Bacardi") violated Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a), by falsely and misleadingly describing the geographic origin of defendant's Havana Club rum product (count I) and falsely stating that it owns the Havana Club trademark in the United States (count II). On September 13, 2006, Bacardi moved to transfer this action to the Southern District of Florida. (D.I.6, 7) On September 22, 2006, Bacardi answered count I and moved to dismiss count II of the complaint. [FN1] (D.I.12, 14) Plaintiff opposes the motion (D.I.17, 18, 19) and defendant has filed its reply. (D.I.20, 21)

FN1. This memorandum order addresses only the motion to transfer.

2. Background. Pernod is an Indiana corporation with its principal place of business in Purchase, New York. (D.I.1, 18) It is a leading producer, importer and marketer of spirits, including rum and vodka. Pernod is the third largest in the spirits industry by sales value and the fourth largest by sales volume. (Id.) Two of Pernod's leading

brands are "Malibu" rum and "Stolichnaya" vodka. Pernod's net sales for fiscal 2006 in the United States were over 1.2 billion. [FN2] (D.I.18)

FN2. According to the affidavit of Thomas R. Lalla, Jr., general counsel and senior vice-president of administration and legal affairs for Pernod. (D.I.18)

2. Bacardi is a Delaware corporation with its headquarters in Miami, Florida. (D.I. 1 at i 5) It is a leading importer and marketer of wine and spirits, including rum and vodka, throughout the United States. Bacardi is the marketing arm of Bacardi Limited, one of the leading importers of wine and spirits, including rum and vodka. (D.I.19, ex. 2) Two of Bacardi's brands are "Bacardi" rum and "Grey Goose" vodka. Bacardi Limited's worldwide annual sales for fiscal 2006 were \$4.55 billion. Bacardi and Pernod are competitors.

3. According to Pernod, in August 2006, Bacardi launched Havana Club rum, describing the rum as the rum that was formerly made in Cuba and sold in the United States prior to 1960. Bacardi further represented that it owned the Havana Club trademark. (D.I. 1 at i 7-9; ex. C) Pernod asserts both of Bacardi's representations are false. Pernod alleges these statements were made as part of Bacardi's nationwide media marketing campaign to launch Havana Club. [FN3]

FN3. Pernod avers that WHYY, originating from Philadelphia, Pennsylvania into Delaware, broadcast a National Public Radio program wherein the alleged false statements were made. Further, the statements appeared in internet news sites, including MSN Money, and in print in the Wall Street Journal. (D.I.1, 19)

4. Bacardi avers that Havana Club is only sold in the State of Florida and is not sold in the State of Delaware. (D.I. 9 i 2) Havana Club is distilled in Puerto Rico based on a recipe provided to Bacardi by the Arechabala family--the Cuban manufactures of Havana Club before 1960. (Id. at i 3) All of Bacardi's executive offices and business operations relating to Havana Club are based in Miami, Florida. (Id. at i 4) Bacardi has no offices, business locations, employees and documents related to Havana Club located in Delaware. Forcing employees to travel to Delaware for trial would, according to Bacardi, disrupt its business operations. The press releases at issue originated from Florida by the corporate communications department. Interviews about Havana Club were done in Miami.

\*2 6. Significantly, Bacardi asserts that, as part of its defense, individuals with pertinent information regarding the history of Havana Club will be called to testify at trial. (D.I.7) These elderly and frail individuals reside in



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Florida. [FN4] (D.I.8)

FN4. According to the declaration of Ramon Maria Arechabala, he had a quadruple bypass in 1989 and an operation for an aorta aneurism in 2000. (D.I.8) He subsequently developed another aneurism and had a blood clot. He takes Coumadin and, despite these health problems, would like to provide testimony regarding the Havana Club trademark, recipe and sale to Bacardi. Arechabala's family manufactured Havana Club before it was confiscated by the Cuban revolutionary government.

7. Standard of Review. Under 28 U.S.C. § 1404(a), a district court may transfer any civil action to any other district where the action might have been brought for the convenience of parties and witnesses and in the interests of justice. Congress intended through § 1404 to place discretion in the district court to adjudicate motions to transfer according to an individualized, case-by-case consideration of convenience and the interests of justice. *Stewart Org., Inc. v. Ricoh Corp.*, 487 U.S. 22, 29, 108 S.Ct. 2239, 101 L.Ed.2d 22 (1988); *Affymetrix, Inc. v. Synteni, Inc.*, 28 F.Supp.2d 192, 208 (D.Del.1998).

8. The burden of establishing the need to transfer rests with the movant "to establish that the balance of convenience of the parties and witnesses strongly favors the defendants." *Bergman v. Brainin*, 512 F.Supp. 972, 973 (D.Del.1981) (citing *Shutte v. Armco Steel Corp.*, 431 F.2d 22, 25 (3d Cir.1970)). "Unless the balance is strongly in favor of a transfer, the plaintiff's choice of forum should prevail". *ADE Corp. v. KLA-Tencor Corp.*, 138 F.Supp.2d 565, 567 (D.Del.2001); *Shutte*, 431 F.2d at 25.

9. The deference afforded plaintiff's choice of forum will apply so long as plaintiff has selected the forum for some legitimate reason. *C.R. Bard, Inc. v. Guidant Corp.*, 997 F.Supp. 556, 562 (D.Del.1998); *Cypress Semiconductor Corp. v. Integrated Circuit Systems, Inc.*, 2001 WL 1617186 (D.Del. Nov.28, 2001); *Continental Cas. Co. v. American Home Assurance Co.*, 61 F.Supp.2d 128, 131 (D.Del.1999). Although transfer of an action is usually considered as less inconvenient to a plaintiff if the plaintiff has not chosen its "home turf" or a forum where the alleged wrongful activity occurred, the plaintiff's choice of forum is still of paramount consideration, and the burden remains at all times on the defendants to show that the balance of convenience and the interests of justice weigh strongly in favor of transfer." *In re M.L.-Lee Acquisition Fund II, L.P.*, 816 F.Supp. 973, 976 (D.Del.1993).

10. The Third Circuit Court of Appeals has indicated that the analysis for transfer is very broad. *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir.1995). Although

emphasizing that "there is no definitive formula or list of factors to consider," *id.*, the Court has identified potential factors it characterized as either private or public interests. The private interests include: "(1) plaintiff's forum preference as manifested in the original choice; (2) defendant's preference; (3) whether the claim arose elsewhere; (4) the convenience of the parties as indicated by their relative physical and financial condition; (5) the convenience of the witnesses but only to the extent that the witnesses may actually be unavailable for trial in one of the fora; and (6) location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum)." *Id.* (citations omitted).

\*3 11. The public interests include: "(1) the enforceability of the judgment; (2) practical considerations that could make the trial easy, expeditious or inexpensive; (3) the relative administrative difficulty in the two fora resulting from court congestion; (4) the local interest in deciding local controversies at home; (5) the public policies of the fora; and (6) the familiarity of the trial judge with the applicable state law in diversity cases." *Id.* (citations omitted).

12. Discussion. Defendant argues that transfer is warranted because Delaware has no connection to this litigation. (D.I.7) Specifically, no material events occurred and no witnesses are located in Delaware. The only connection to this forum is that Delaware is Bacardi's state of incorporation. Considering the inconvenience to witnesses and business operations, Bacardi urges transfer to the Southern District of Florida, which has the strongest ties to the events and witnesses. Specifically, all witnesses reside in Florida and the consumers alleged to have been deceptively induced into purchasing Havana Club also are in Florida. All relevant documents are located at the Bacardi business in Miami, Florida.

13. Pernod opposes the motion on several grounds. (D.I.17) First, Pernod is entitled to litigate in its choice of forum. Pernod would be inconvenienced by having to litigate this action in Florida because New York, its principal place of business, is closer to Delaware. Second, since Bacardi is a Delaware corporation enjoying all the benefits and protections of this State's laws, it cannot credibly contend that litigation here is inconvenient. Finally, proceeding in Delaware will not cause a financial hardship to a huge company such as Bacardi.

14. Weighing the arguments against the Jumara balancing test, the court finds that the asserted advantages of moving the case to the Southern District of Florida are insufficient to warrant a transfer. Defendant's complaints about litigating here are outweighed by the fact that



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Bacardi has enjoyed the benefits and protections of incorporation in Delaware and that the State has an interest in litigation regarding companies incorporated within its jurisdiction.

15. Bacardi has demonstrated that it would be inconvenient for some of its witnesses to provide testimony in Delaware. Considering that discovery can be conducted at any location convenient to the parties and their employees, the only event that will take place in Delaware is the trial. The travel expenses and inconveniences incurred for that purpose, by a Delaware defendant conducting a world-wide business, is not overly burdensome. From a practical standpoint, much of the testimony presented at trial these days is presented via recorded depositions, as opposed to witnesses traveling and appearing live. There certainly is no obstacle to Bacardi embracing this routine trial practice.

15. Conclusion. For the reasons stated, defendant's motion to transfer (D.I.6) is denied.

2006 WL 3755452 (D.Del.)

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Slip Copy, 2007 WL 1648908 (E.D.Mich.)

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Schering Corp. v. Caraco Pharmaceutical Laboratories, Ltd.

E.D.Mich.,2007.

Only the Westlaw citation is currently available.

United States District Court,E.D.

Michigan,Southern Division.

SCHERING CORPORATION, Plaintiff,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD. and Sun Pharmaceutical Industries, Ltd.,

Defendants.

No. 06-14386.

June 6, 2007.

Gerald J. Flattmann, Jr., Kirkland & Ellis, New York, NY, Jordan S. Bolton, Clark Hill, Detroit, MI, Ronald A. King, Clark Hill, Lansing, MI, for Plaintiff.

Moheeb H. Murray, Raymond M. Kethledge, Bush, Seyferth, Troy, MI, Michael K. Nutter, Winston and Strawn, Chicago, IL, for Defendants.

#### ORDER

JULIAN ABELE COOK, JR., United States District Court Judge.

\*1 This case involves a contention by the Plaintiff, Schering Corporation ("Schering"), that both of the Defendants, Sun Pharmaceutical Industries, Ltd. ("Sun"), and Caraco Pharmaceutical Industries, Ltd. ("Caraco"), infringed upon its ownership rights to U.S. Patent No. 6,100,274 ("the '274 patent"), which covers pharmaceutical compositions for the oral administration of a drug commonly known as "desloratadine" and marketed to the general public under the Clarinex trademark. All of these charges have been denied by the Defendants.

#### I.

Prior to the commencement of this lawsuit, the Sun filed an Abbreviated New Drug Application

("ANDA") No. 78-539 with the Food and Drug Administration (FDA), seeking to obtain a generic version of Clarinex. All together, fifteen ANDAs FNI were submitted to the FDA by or on behalf of twenty-one pharmaceutical entities during mid-2006. According to Schering, each of these ANDAs have sought, and continue to seek, approval from the FDA to produce and sell generic products that contain desloratadine prior to the expiration of its '274 patent. Each application, including Sun's petition to the FDA, contained claims that the '274 patent is invalid and/or would not infringe upon the manufacture or sale of the proposed generic products.

FNI. An Abbreviated New Drug Application, or ANDA, is an application that is filed with the FDA for generic drug approval of an existing licensed medication or approved drug. The ANDA contains data, which when submitted to the FDA Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a low cost alternative to the American public.

#### II.

On September 29, 2006, Schering filed a lawsuit in the United States District Court for the District of New Jersey, in which it named all of those corporate entities that had filed ANDAs as defendants, including Sun and Caraco. The following week (October 5, 2006), Schering filed the instant lawsuit in the Eastern District of Michigan against Sun and Caraco. A comparison of these two lawsuits reveals that the allegations in both are substantively identical, with the only major difference being that the New Jersey proceeding involves twenty-one defendants whereas the case in Michigan has only two defendants.

Schering contends that these two lawsuits were



filed in an effort to receive the statutory protections to which it is entitled under the “Hatch-Waxman Act.”<sup>FN2</sup> Under the terms of this legislation, if an original patent owner files a lawsuit within forty-five days after receiving notice of an allegedly infringing ANDA, approval by the FDA is automatically delayed for a period of thirty months, or until the court determines that the patent has not been infringed, whichever occurs first. 21 U.S.C. § 355(c)(3)(c); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677-78, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990).

FN2. The Drug Price Competition and Patent Term Restoration Act is informally known as the “Hatch-Waxman Act.” It is a 1984 federal law which sets forth the process by which potential marketers of generic drugs can file applications for approval with the Food and Drug Administration.

Schering acknowledges that it initially filed the lawsuit in New Jersey where it prefers to litigate this dispute. However, Schering submits that, acting upon the concern that the Defendants would challenge personal jurisdiction in New Jersey, it initiated legal proceedings in Michigan.<sup>FN3</sup> On January 8, 2007, Schering filed a motion, in which it asked this Court to stay the proceedings in Michigan to allow the judge in New Jersey to resolve the Defendants' pending jurisdictional challenge.<sup>FN4</sup> Sun and Caraco have collectively opposed Schering's request for relief. On March 30th, Schering filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) pursuant to 28 U.S.C. § 1407<sup>FN5</sup> which, if granted, would consolidate the New Jersey and Michigan cases. On April 23, 2007, the New Jersey court (1) issued a *sua sponte* order which stayed the case until such time as Schering's motion to consolidate is resolved by the JPML, and (2) denied the Defendants' motion to dismiss without prejudice.

FN3. The lawsuit in Michigan can be accurately described as a protective measure. According to Schering, it feared that if (1) the Defendants' jurisdictional challenge in

New Jersey is successful and (2) the legal proceedings had not been initiated in Michigan, it would have lost the benefit of the thirty month stay of the ANDA that had been filed by the Defendants.

FN4. The parties presented oral arguments in support of their respective positions during a hearing on April 10, 2007.

FN5. This motion was filed with the JPML on March 30, 2007.

### III.

\*2 A motion to stay the proceedings is not found in the Federal Rules of Civil Procedure. However, the inherent power of a court to control the disposition of the cases on its docket in an efficient and timely manner includes the authority to stay proceedings. *Landis v. North American Co.*, 299 U.S. 248, 254 (1936). When addressing a party's request for a stay order, a court must exercise its judgment by weighing the competing interests and maintaining an even balance. *Id.* at 254-55. The party who seeks to obtain a stay must “make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to someone else.” *Id.* at 255. The Sixth Circuit Court of Appeals has also stated that “the burden is on the party seeking the stay to show that there is a pressing need for delay, and that neither the other party nor the public will suffer harm from entry of the order.” *Ohio Envtl. Council v. U.S. District Court*, 565 F.2d 393, 396 (6th Cir.1977).

Ordinarily, when there is more than one action involving the same patent, the “first to file rule” gives priority to the first lawsuit while the second action is stayed. *Aventis Pharma v. Lupin Ltd.*, 403 F.Supp.2d 484 (E.D.Va.2005). A district court in the Eastern District of Virginia recently explained that the “‘first to file’ rule applies in two contexts ... [where] (1) either one patent is involved but there are multiple defendants in different forums, or (2) the defendant files its own ‘mirror-image’ infringement action in another forum in response to



being sued.” *Aventis* at 489.

The case law on ANDA litigation is not settled, and there is no definitive guidance to those district courts judges who are charged with handling “protective” lawsuits such as the one at issue here. It is unclear precisely how the “first to file” rule applies in ANDA lawsuits. Thus, in the absence of any definitive guidance, the Court must examine the prejudice, if any, that would be caused to either side from proceeding in this forum or from granting a stay order.

The 1984 “Hatch-Waxman Act” provides a directive to the parties which optimistically states that they “shall reasonably cooperate in expediting the action.” 21 U.S.C. § 3455(c)(3)(c). Here, Schering and the Defendants have accused each other of delaying the proceedings in bad faith and in contravention of the “Hatch-Waxman Act.” While each side has vigorously asserted that the other party is causing an unfair delay in the progression of this litigation, the Court has not received any evidence which supports either position on the issue of bad faith.

#### IV.

The Defendants contend that they will suffer extreme prejudice if the action in Michigan is stayed. While this lawsuit and the action in New Jersey are pending, Sun's ANDA application is automatically stayed for a period of thirty months or until the cases are resolved, whichever occurs first. Thus, the longer it takes to resolve the dispute in this case, the longer the Defendants will be prevented from producing and potentially profiting from a generic version of Clarinex. However, the recent stay decision by the New Jersey court has made it clear that a final resolution of the dispute over Sun's ANDA will probably not occur in the near future.

\*3 Schering maintains that if it is required to litigate identical issues in parallel actions, it will be forced to incur an unwarranted duplication of effort and expense. Noting that there are nineteen other

defendants in the New Jersey action, Schering contends that the issues in dispute with all of these challengers are exactly the same which-in the absence of a stay order from this Court-would cause it to expend a substantial amount of its resources to engage in separate discovery in the two jurisdictions. Moreover, Schering asserts that staying this proceeding to allow the New Jersey litigation to move forward expeditiously will conserve judicial resources.

The Court, while genuinely concerned that the finalization of this jurisdictional issue by the New Jersey court may not be soon, finds that it has no other reasonable alternative but to grant Schering's motion for a stay. In rendering this decision, the Court is persuaded that the danger of unfair prejudice to Schering is substantial. In addition, the probable inefficiency and the potential for the misuse of the limited resources of the judiciary that would occur if this litigation moved forward in Michigan while the case in New Jersey was stayed would be significant. Fed.R.Civ.P. 403. As a result, the Court must, and does, grant Schering's motion for a stay. The case is stayed pending a final determination by the JPML regarding consolidation of the cases.

IT IS SO ORDERED.

E.D.Mich., 2007.

Schering Corp. v. Caraco Pharmaceutical Laboratories, Ltd.

Slip Copy, 2007 WL 1648908 (E.D.Mich.)

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Versus Technology, Inc. v. Hillenbrand Industries, Inc.

W.D.Mich.,2004.

Only the Westlaw citation is currently available.

United States District Court,W.D.

Michigan,Southern Division.

VERSUS TECHNOLOGY, INC., Plaintiff,

v.

HILLENBRAND INDUSTRIES, INC., Hill-Rom Services, Inc., Hill-Rom Company, Inc., Visonic Technologies Ltd, and VT Americas, Inc., Defendants.

**No. 1:04-CV-168.**

Nov. 23, 2004.

Jon G. March, Craig H. Lubben, James R. Peterson, Salvatore W. Pirrotta, George Pazuniak, Gerard M. O'Rourke, for Plaintiff.

Timothy J. Abeska, Carl Edward Moore, Eugene J. Rath, III, Douglas H. Siegel, Lynn Campbell Tyler, for Defendants.

### **OPINION**

GORDON J. **QUIST**, District Judge.

\*1 Plaintiff, Versus Technology, Inc. ("Versus"), filed its complaint in this case on March 15, 2004, against Defendants, Hillenbrand Industries, Inc. ("Hillenbrand"), HillRom Services, Inc. ("HRS"), and Hill-Rom Company, Inc. ("HRC") (collectively referred to as the "Hillenbrand Defendants"), and Visonic Technologies Ltd. ("Visonic"), and Visonic Inc. Pursuant to a stipulated Order entered on June 3, 2004, Versus filed an amended complaint amending the caption to substitute VT Americas, Inc. ("VTA") for Visonic, Inc. as a defendant. Presently before the Court are the Hillenbrand Defendants' motions to transfer venue, to dismiss for failure to join an indispensable party, to dismiss Counts II, III, and VI of Versus's amended complaint, and to strike portions of the declaration of Gary T. Gaisser. Also before the Court are VTA's motion to dismiss for lack of

personal jurisdiction and improper venue or, in the alternative, to transfer venue, and Visonic's motion to dismiss for lack of personal jurisdiction.

The Court heard oral argument on these motions by telephone on August 26, 2004. At the conclusion of the hearing, the Court granted the Hillenbrand Defendants' motion to dismiss Counts II, III, and VI with respect to Versus' misrepresentation and innocent misrepresentation claims for failure to comply with [Fed.R.Civ.P. 9\(b\)](#), but allowed Versus to file an amended complaint to plead those claims with specificity. The Court took the remainder of that motion and the other motions under advisement. Versus has now filed a motion for leave to file a second amended complaint and supplemental complaint which, in addition to including more specific allegations in the misrepresentation claims, adds Elpas Electro-Optic Systems Ltd. as a defendant and identifies more precisely the patent infringement claims previously alleged against Visonic and VTA. Visonic and VTA oppose this motion and have filed a response.

For the reasons set forth below, the Court will allow Versus' proposed amendment but will transfer the case to the Middle District of North Carolina based upon the rule of comity among federal courts known as the "first-to-file" rule.

### **I. Background**

Versus is a Delaware corporation with its principal place of business in Traverse City, Michigan. Versus develops and markets products that use infrared and radio frequency technology in various applications, including systems for locating and tracking people and equipment. Versus' locating systems are used in "nurse call" systems in hospitals. "Nurse call" systems are commonly associated with hospital beds and are used to provide notification during patient emergencies. Versus sells its locating systems directly to hospitals and to third-party original equipment manufacturers. Versus is the owner of United States [Patent 5,027,314](#) ("the



'314 Patent"), entitled "Apparatus and Method for Position Reporting," and United States Patent 6,154,139 ("the '139 Patent"), entitled "Method and System for Locating Subjects within a Tracking Environment." Versus is the exclusive licensee of United States Patent 5,572,195 ("the '195 Patent"), entitled "Sensory and Control System for Local Area Networks," and United States Reissue Patent 36,791 ("the '791 Patent"), entitled "Location System Adapted for Use in Multipath Environments." These patents cover the technology used in Versus' tracking and locating systems.

\*2 Hillenbrand is a Delaware corporation with its principal place of business in Batesville, Indiana. HRS and HRC are both Delaware corporations with principal places of business in Batesville, Indiana. Hillenbrand is a publicly-traded holding company, and HRS and HRC are two of its wholly-owned subsidiaries. HRC is a major supplier through sales, rentals, and service of hospital products, including beds, therapy surfaces, stretchers, furniture, communications systems and head-wall systems. For several years, HRC and/or HRS has marketed throughout the United States "nurse call" systems that use integrated locating systems. HRC has marketed and sold the COMposer Communication System, which includes locator badges, and more recently has developed the COMlinx System, which includes or uses the COMlinx Local Positioning Module. HRS is the owner of now-expired United States Patent Reexamination Certificate No. RE 35,035 ("the '035 Patent"), entitled "Locating System and Method," and United States Patent No. 6,462,656 ("the '656 Patent"), entitled "Personnel and Asset Tracking Method and Apparatus," both of which cover the technology used in HRC's locating systems.

Visonic is an Israeli holding company that owns three companies located in Israel. These companies manufacture integrated identification and facility management solutions incorporating local positioning, security, access control, and asset management. Elpas Electro-Optic Systems ("Elpas"), one of the companies, manufactures a product known as the Elpas Local Positioning System,

which is used in the COMlinx system. (Radomsky Decl. ¶ 4, attached to Def. Visonic's Br. Supp. Mot. Dismiss.) Elpas sells this product in the United States through VTA, its sole distributor of the product in the United States. (*Id.*) VTA, in turn, sells the product to HRC for use in the COMlinx system. (*Id.*) VTA, a subsidiary of Elpas, is a Delaware corporation with its principal place of business in Bloomfield, Connecticut. (*Id.* ¶ 3.)

On December 30, 2003, HRS filed a complaint in the United States District Court for the Middle District of North Carolina ("MDNC") against Versus and three of its distributors, A4 Health Systems, Inc., Healthcare Information Technology, Inc., and Surgical Information Systems, LLC. According to the Hillenbrand Defendants, HRS filed its complaint in the MDNC because Versus and one of its distributors installed an infringing system at Duke University Hospital located in the MDNC. The complaint alleged that Versus and its distributors are infringing the '656 Patent and had previously infringed the expired '035 Patent. Instead of serving the complaint, on January 6, 2004, William A. Morrison, HRS's Senior Intellectual Property Counsel, sent a copy of the complaint, a draft settlement agreement, and a letter outlining HRS's infringement claim, including damages, to Versus' President and CEO, Gary T. Gaisser. (Morrison Decl. ¶ 2 & Ex. A, Hillenbrand Defs.' Br. Supp. Mot. Transfer Ex. 4.) Williams indicated that HRS was serious about pursuing its infringement claims but extended an invitation to discuss an amicable resolution of the matter. Versus responded on February 12, 2004, through a letter from its counsel, Robert Tuttle, requesting additional information from HRS regarding its infringement claims. (*Id.* ¶ 3 & Ex. B.) After exchanging correspondence several more times, representatives of HRS and Versus met to discuss the North Carolina lawsuit on or about March 5, 2004. (*Id.* ¶ 6; Gaisser Decl. ¶ 11, Pl.'s Br. Resp. Hillenbrand Defs.' Mot. Transfer Ex. A.) The parties did not reach an agreement at the meeting.

\*3 Versus filed its complaint in this case on March 15, 2004. Versus alleges that in early 2000, Versus and Hillenbrand began negotiating a rela-



tionship in which: (1) Versus would grant Hillenbrand a license to use Versus' patents, which Hillenbrand was then infringing; (2) Hillenbrand would acquire an equity interest in Versus; (3) the parties would execute a development agreement, pursuant to which Versus would overlay its system on the existing Hillenbrand nurse call system and would develop new products for Hillenbrand over a five-year period; and (4) the parties would execute a supply agreement pursuant to which Versus would supply locating products to Hillenbrand on an exclusive basis for five years. (1st Am.Compl. ¶ 15.) Versus alleges that the parties signed a "Non-Exclusive Patent License Agreement" (Versus and HRS) and a Stock Purchase Agreement (Versus and Hillenbrand) on September 1, 2000. (*Id.* ¶ 16.) According to Versus, Hillenbrand insisted that Versus execute the License Agreement and Stock Purchase Agreement first and represented that it would subsequently execute the five-year supply and development agreements. Versus claims that, contrary to these representations, Hillenbrand did not finalize the remaining agreements and did not overlay Versus' locating system onto Hillenbrand's nurse call systems. (*Id.* ¶¶ 19, 20.) Instead, Versus alleges, Hillenbrand began purchasing the locating technology for its COMLinX Local Positioning Module from Visonic (or VTA). (*Id.* ¶ 20.)

Count I of the first amended complaint alleges that the Hillenbrand Defendants and Visonic (VTA) have infringed at least one claim of each of the '314, '195, '139, and '791 Patents by making, using, selling and/or offering to sell COMLinX outside the scope of the License Agreement. Counts II, III, IV, and V allege claims for misrepresentation, innocent misrepresentation, breach of contract, and promissory estoppel against the Hillenbrand Defendants based upon their failure to finalize the remaining agreements and to overlay their nurse call system with Versus' locating system. Count VI alleges a claim against the Hillenbrand Defendants and Visonic for infringement of Versus' patents in the event that the License Agreement is rescinded based upon the misrepresentation claims. Finally, Count VIII alleges various antitrust violations by the Hillenbrand Defendants.

On April 7, 2004, HRS filed an amended complaint in the North Carolina case adding Hillenbrand and HRC as plaintiffs and adding five declaratory judgment counts. In the declaratory judgment counts, Hillenbrand seeks a declaration that: (1) Hillenbrand is not infringing Versus' patents and Versus has released any claims for infringement against Hillenbrand as a result of the License Agreement; (2) the License Agreement is not rescindable and Hillenbrand has not breached the License Agreement; (3) Hillenbrand never made any enforceable agreement with or representations to Versus; (4) Versus has no claim against Hillenbrand for misrepresentation, innocent misrepresentation, or promissory estoppel; and (5) Hillenbrand has not committed any antitrust violation against Versus. On April 26, 2004, Versus and the other defendants in the North Carolina case moved to dismiss Counts II through VI of Hillenbrand's amended complaint. To this Court's knowledge, the North Carolina court has not ruled on that motion as of the date of this Opinion.

## II. Discussion

\*4 As noted above, the Court has before it motions raising personal jurisdiction and venue issues as well as dispositive issues. In addition, Versus requests leave to file a second amended and supplemental complaint which, among other things, clarifies Versus' patent infringement claims against Visonic and VTA. The Court will address Versus' motion to amend first and then consider the Hillenbrand Defendants' motion to transfer venue. Because the Court concludes that the case is governed by the first-to-file rule and that transfer is appropriate pursuant to that rule, the Court will not consider VTA's and Visonic's motions to dismiss for lack of personal jurisdiction and the Hillenbrand Defendants' dispositive motions.

### A. Motion to Amend

Versus seeks leave to file a second amended and supplemental complaint. Versus' proposed amendment contains additional factual allegations



in order to comply with [Rule 9\(b\)](#) on the fraud and misrepresentation claims as required by the Court's August 26, 2004, Order. In addition, the proposed amendment adds Elpas as a defendant in this lawsuit and contains new allegations which identify Visonic's EIRIS Local Positioning System ("EIRIS LPS") as an infringing product separate from the COMLinX system identified in the amended complaint.

Under [Rule 15\(a\) of the Federal Rules of Civil Procedure](#), once a responsive pleading has been filed, "a party may amend the party's pleading only by leave of court or by written consent of the adverse party." [Fed.R.Civ.P. 15\(a\)](#). [Rule 15\(a\)](#) also provides that "leave shall be freely given when justice so requires." *Id.* The mandate that "leave shall be freely given" embodies "the principle that cases 'should be tried on their merits rather than the technicalities of the pleadings.'" *Moore v. City of Paducah*, 790 F.2d 557, 559 (6th Cir.1986) (per curiam) (quoting *Tefft v. Seward*, 689 F.2d 637, 639 (6th Cir.1982)). However, a court is not obliged to grant an amendment simply because a motion is made. See *Johnson v. Ventra Group, Inc.*, No. 96-1463, 1997 WL 468332, (6th Cir. Aug. 13, 1997) (per curiam). "A motion to amend a complaint should be denied if the amendment is brought in bad faith, for dilatory purposes, results in undue delay or prejudice to the opposing party, or would be futile." *Crawford v. Roane*, 53 F.3d 750, 753 (6th Cir.1995); see also *Foman v. Davis*, 371 U.S. 178, 182, 83 S.Ct. 227, 230 (1962).

Visonic and VTA argue that the Court should deny the motion because Versus has already had sufficient time to investigate its claims in this case and should have been aware that Elpas was a party to the supply agreement between HRS and VTA at the time it amended its complaint to add VTA as a defendant. Visonic and VTA further argue that by proposing yet another amendment, Versus is changing the complexion of the case by expanding the scope of the alleged infringement beyond the scope of the COMLinX product, even though Versus alleged to VTA's predecessor as early as 2001 that Elpas products infringed Versus patents. Visonic

and VTA assert that Versus seeks to add Elpas and the EIRIS LPS product as an infringing product merely to avoid dismissal based upon lack of personal jurisdiction.

\*5 The Court will grant Versus' motion and allow it to file its amended complaint because Visonic and VTA have not cited a sufficient basis to deny the motion. The Sixth Circuit has recently observed: "Delay by itself is not sufficient reason to deny a motion to amend. Notice and substantial prejudice to the opposing party are critical factors in determining whether an amendment should be granted." *Bridgeport Music, Inc. v. Dimension Films*, 383 F.3d 390, 402 (6th Cir.2004) (quoting *Head v. Jellico Hous. Auth.*, 870 F.2d 1117, 1123 (6th Cir.1989) (quoting *Hageman v. Signal L.P. Gas, Inc.*, 486 F.2d 479, 484 (6th Cir.1973))). At most, Visonic and VTA have shown some delay, but they have not shown significant prejudice. That is, the amendment comes at an early stage in the litigation: a Rule 16 conference has not been held and no scheduling order has been entered and, except for the limited discovery relating to personal jurisdiction, discovery on the substantive issues has not yet begun. See *Risteen v. Youth For Understanding, Inc.*, 245 F.Supp.2d 1, 4-5 (D.D.C.2002) (finding no prejudice to the defendants where the motion to amend was filed before entry of a scheduling order and before the commencement of discovery). Moreover, Versus has provided at least a plausible explanation for not adding Elpas as a defendant at an earlier time, namely, some confusion regarding the relationship among Visonic, its wholly-owned entities (VTA and Elpas), and VTA's predecessor, Elpas North America, Inc. In any event, the amendment will not result in substantial prejudice to Visonic and VTA, and it is consistent with the interests of justice in the prompt resolution of disputes because, at least at this point, the EIRIS LPS product and the COMLINX product appear to be the same.

## B. Motion to Transfer

The Hillenbrand Defendants have moved for a



transfer of venue to the MDNC pursuant to 28 U.S.C. § 1404(a). As part of their motion to transfer, the Hillenbrand Defendants have invoked the first-to-file rule, which provides a separate basis for transfer.

The first-to-file rule is a generally recognized doctrine of federal comity which provides that “ ‘as a principle of sound judicial administration, the first suit should have priority,’ absent special circumstances.” *Kahn v. Gen. Motors Corp.*, 889 F.2d 1078, 1081 (Fed.Cir.1989) (quoting *William Gluckin & Co. v. Int’l Playtex Corp.*, 407 F.2d 177, 178 (2d Cir.1969)). The rule allows a district court to decline jurisdiction over an action when a complaint involving the same parties and issues has already been filed in another district. *Pacesetter Sys., Inc. v. Medtronic, Inc.*, 678 F.2d 93, 94-95 (9th Cir.1982). The rule promotes the conservation of judicial resources and the comprehensive disposition of litigation by avoiding duplication of time and effort, interference in another court’s affairs, conflicting results, and piecemeal resolution of issues that call for a uniform result. See *Sutter Corp. v. P & P Indus., Inc.*, 125 F.3d 914, 917 (5th Cir.1997). A court determines whether the first-to-file rule applies by examining: “(1) the chronology of the actions; (2) the similarity of the parties involved; and (3) the similarity of the issues at stake.” *Plating Resources, Inc. v. UTI Corp.*, 47 F.Supp.2d 899, 903-04 (N.D. Ohio 1999) (citing *Alltrade, Inc. v. Uniweld Prods., Inc.*, 946 F.3d 622, 628 (9th Cir.1991)); see also *Zide Sport Shop of Ohio, Inc. v. Ed Tobergte Assocs., Inc.*, No. 00-3183, 2001 WL 897452, at \*3 (6th Cir. July 31, 2001) (“The rule provides that when actions involving nearly identical parties and issues have been filed in two different district courts, ‘the court in which the first suit was filed should generally proceed to judgment.’”) (quoting *In re Burley*, 738 F.2d 981, 988 (9th Cir. 1984)). The claims in the two cases need not be identical; only substantial similarity of issues or substantial overlap in the cases need be shown. See *Datamize, Inc. v. Fidelity Brokerage Servs., LLC*, No. 2:03-CV-321-DF, 2004 WL 1683171, at \*3-4 (E.D.Tex. Sept. 5, 2003) (citing *Superior Sav. Ass’n v. Bank of Dallas*, 705

F.Supp. 326, 329 (N.D.Tex.1989)); *Plating Resources, Inc.*, 47 F.Supp.2d at 903 (stating that “courts should invoke the rule when two suits involving substantially the same parties and purpose have been filed in a concurrent jurisdiction”). Similarly, the rule does not require identical parties in both cases. See *Save Power Ltd. v. Syntek Fin. Corp.*, 121 F.3d 947, 951 (5th Cir.1997) (stating that “[c]omplete identity of parties is not required” to apply the rule); *Hartford Accident & Indem. Co. v. Margolis*, No. 90-16626, 1992 WL 43484, at \*1 (9th Cir. Mar. 5, 1992) (“Absolute identity of parties in the two cases is not required.”); *Homas & Betts Corp. v. Hayes*, 222 F.Supp.2d 994, 996 (W.D.Tenn.2002) (stating that “precise identity of the parties to both actions is not required”) (citing *Plating Resources, Inc.*, 47 F.Supp.2d at 904); *EBW, Inc. v. Environ Prods., Inc.*, No. 1:96-cv-144, 1996 WL 550020, at \*3 (W.D.Mich. July 8, 1996) (stating that “a precise identity of parties is simply not required”).

\*6 Complicating the Court’s resolution of this issue somewhat is the fact that Versus has filed a motion to dismiss Counts II-VI of the Hillenbrand Defendants’ amended complaint in the MDNC action—the declaratory judgment claims that mirror Versus’ claims in this case—based upon the first-to-file rule. Further muddying the waters is the parties’ dispute regarding whether this action or the MDNC action should be considered the first-filed action. This issue is of consequence because it is generally accepted that the court which first obtained jurisdiction should determine whether to apply the first-to-file rule. See *Daimler Chrysler Corp. v. Gen. Motors Corp.*, 133 F.Supp.2d 1041, 1044 (N.D. Ohio 2001) (“Leaving the decision of the first to file dispute to the court in which the first case was filed makes good sense, as it establishes a bright line rule, which is as easy to apply as it is to understand.”); *Kimberly-Clark Corp. v. McNeil-PPC, Inc.*, 260 F.Supp.2d 738, 741 (E.D.Wis.2003) (holding that “where identical, or nearly identical, actions are pending before two courts, it is the court in which the action was first filed that makes the determination of which court is to hear the case”). The present circumstances thus pose a risk of two



courts reaching different conclusions based upon a procedural rule designed to maximize judicial economy and avoid inconsistent outcomes. However, in light of the parties' comments at oral argument indicating that the MDNC may be waiting for a decision from this Court before addressing Versus' motion to dismiss in that case, this Court will address the issue.

Chronologically, the MDNC complaint was filed first in time, which suggests that the MDNC action was the first-filed action. See *Kimberly-Clark Corp.*, 260 F.Supp.2d at 740-41 (“The issue, however, is not which of the claims was filed first, but rather which action was filed first. And as to that issue there is no dispute. The action McNeil commenced in New Jersey District Court was filed first.”). Versus contends that this case was the first-filed action because the claims were first made in this Court and this case includes parties that are not present in the MDNC action. Versus points out that the MDNC case was limited to patent infringement claims by HRS against Versus and three of its distributors, while this action includes patent infringement claims based upon different patents, as well as misrepresentation, breach of contract, and antitrust claims against HRS, HRC, Hillenbrand, and the Vissonic Defendants.

Although Versus is correct that its claims were first raised in this case, several courts have held that a subsequently-filed amendment is prior to an earlier complaint where the amendment is made in the first-filed action. Some courts have relied upon the relation-back doctrine under Fed.R.Civ.P. 15(c) in order to conclude that the amendment was first-filed. See, e.g., *Nat'l Foam, Inc. v. Williams Fire & Hazard Control, Inc.*, No. CIV. A. 97-3105, 1997 WL 700496, at \*4-7 (E.D.Pa. Oct. 29, 1997). The Second Circuit, and several other courts following its lead, has held that the first-filed rule applies in any case, where a plaintiff amends its complaint to add claims raised in a second-filed suit in another district. In *Mattel, Inc. v. Louis Marx & Co.*, 353 F.2d 421 (2d Cir.1965), Marx sued Mattel in the District of New Jersey seeking a declaration of non-infringement and invalidity of Mattel's trademark.

Soon thereafter, Mattel filed suit against Marx in the Southern District of New York alleging trademark infringement and a claim for patent infringement. Marx responded by amending its complaint in the New Jersey action to add a count for declaratory judgment of non-infringement and invalidity of the patent at issue in the New York action. The parties filed motions in both courts seeking a stay of the other parties' actions. The New York court enjoined Marx from proceeding in the New Jersey action because the New York action was the first action to pose all of the issues between the parties. The Second Circuit held that this “basic principle” was correct, but concluded that the district court should have applied it in favor of the first-filed New Jersey action:

\*7 The New Jersey action was the first to bring both parties into court and the Marx complaint, as amended prior to the time Judge Sugarman heard argument on the Mattel motion to stay the New Jersey action, included the identical issues as the Mattel complaint in the New York action: validity and infringement both of the patent and of the trademark. The fact that these issues were not all spelled out in the New Jersey action until Marx had amended its complaint is immaterial.... Thus, the New Jersey suit was the first suit which made possible the presentation of all the issues and which, by amendment of the complaint did raise all the substantial issues between the parties.

*Id.* at 424. Accord *GT Plus, Ltd. v. Ja-Ru, Inc.*, 41 F.Supp.2d 421, 424 (S.D.N.Y.1998) (stating that “[b]y virtue of Ja-Ru's amended complaint, the issues in the New York action are no different than the issues in the Florida action, only fewer in number”); *Ainsworth v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 298 F.Supp. 479, 480 (W.D.Okla.1969) (“This suit was filed prior to the Texas action, and Defendants attempt to extricate themselves from the application of the [first-to-file] rule by pointing out that the issues of this case which are similar to those of the Texas case were not raised until plaintiffs amended their Complaint subsequent to the filing of the Texas action. However, this circumstance of amendment is not material in determining priority.”).



In *SAES Getters S.P.A. v. Aeronex, Inc.*, 219 F.Supp.2d 1081 (S.D.Cal.2002), the court was confronted with the issue of whether to give priority to a second-filed action in another court which sought a declaration of non-infringement or to the defendant's proposed counterclaim in the first-filed case before it alleging infringement of the same patent at issue in the second-filed action. Relying on *Mattel, Inc.*, in part, the court concluded that the proposed counterclaim, although filed after the second-filed suit, had priority, because "the forum with priority is the one where the parties initially sued each other, even if the parties raise a different claim in a subsequently filed suit in a different forum"*Id.* at 1090.

The Court concludes that the rationale in *Mattel, Inc.* makes good sense because it facilitates the policies of the first-to-file rule by allowing the first court in which all issues are raised to determine how the cases should proceed. Versus has not cited any authority to the contrary, and the Court finds no reason to reject this reasoning. Although this rationale provides a sufficient basis for this Court to defer to the MDNC action as the first-filed action, this result is also proper because, while the claims in the two cases are not exactly the same, there is ample basis for finding a substantial overlap between the cases. With regard to issues or claims, patent infringement claims are a central focus of both cases and the patents at issue are similar. Versus asserts that there is no similarity because the patents in the two suits "are different patents that were issued at different times to different inventors, and the patents cover different technologies." (Gaisser Decl. ¶ 23.) On the other hand, the summary chart prepared by the Hillenbrand Defendants comparing the titles, abstracts, and excerpts from the written descriptions of HRS's and Versus' patents shows that while the patents may be different, they involve similar technology, i.e., locating systems for assets and personnel using infrared and radio signals, and are closely related. The court's observations in *SAES Getters S.P.A.* are particularly relevant here:

\*8 Just a cursory glance over both patents reveals that they are markedly similar. Both patents

claim to provide a method for purifying gases, and both use what appears to be a similar method for doing so. The Court believes that it will be important for the consistent interpretation of these two similar patents to have one court, rather than two, interpret them. Having a single court conduct the *Markman* hearings for both patents will ensure that the court is familiar with all the potential overlap (if any) in the claims made by the two patents. Furthermore, if the issues related to both patents are presented to one court, the parties can raise any issues of invalidity stemming from the relationship between the two patents before a court which will be well-versed in the technology presented by both patents. Thus, by bringing both patent claims before one court, the possibility of inconsistent judgments should be substantially minimized, if not removed.

*SAES Getters S.P.A.*, 219 F.Supp.2d at 1092. Based upon a similar rationale, the Eastern District of Virginia recently transferred to this Court a patent infringement case, even though the patents were not the same as those in the first-filed case before this Court, because the patents in both cases involved the same "interactive whiteboard" technology and "[l]itigating this singular issue in two different courts could result in conflicting judgments, undermining the enforcement of a court's decision." *Smart Techs., Inc. v. PolyVision Corp.*, No. 3:04CV545, slip op. at 5 (E.D.Va. Oct. 20, 2004).

There is also sufficient similarity between the parties to warrant the application of the first-to-file rule. Versus says that there is little similarity because its distributors are involved in the MDNC action but not here, and HRS and Versus are the only parties common to both suits. However, HRS is closely related to HRC and Hillenbrand because Hillenbrand is the parent and HRS and HRC are wholly-owned subsidiaries of Hillenbrand. In addition, while the distributors are present only in the MDNC action, they are only peripheral to the main dispute between HRS and Versus because their involvement is limited to purchasing and/or reselling the accused device rather than manufacturing it. See *Corry v. CFM Majestic Inc.*, 16 F.Supp.2d 660, 664



(E.D.Va.1998). Finally, the Visonic Defendants' presence in this suit does not detract from the similarity between the two suits because, as the supplier(s) of an accused product to HRS, the Visonic Defendants are essentially in the same position as HRS.

Based upon its conclusion that the MDNC is the first-filed court and that there is a substantial likelihood of overlap between the cases, the Court determines that the most appropriate course of action is to transfer this case to the MDNC to determine how the two cases should proceed. *See Cadle Co. v. Whataburger of Alice, Inc.*, 174 F.3d 599, 605-06 (5th Cir.1999) (holding that the district court properly transferred the second-filed case to the first-filed court after finding a likelihood of a substantial overlap between the two cases) (citing *Mann Mfg. Inc. v. Hortex, Inc.*, 439 F.2d 403, 407 (5th Cir.1971)).

### III. Conclusion

\*9 For the foregoing reasons, the Court will grant Versus' motion to file a second amended and supplemental complaint and will grant the Hillenbrand Defendants' motion to transfer venue upon the grounds that the MDNC action is the first-filed action. In light of the transfer, the Court will leave the decision on the Hillenbrand Defendants' motions to dismiss and Visonic's motion to dismiss for lack of personal jurisdiction to the MDNC.

W.D.Mich.,2004.

Versus Technology, Inc. v. Hillenbrand Industries, Inc.

Not Reported in F.Supp.2d, 2004 WL 3457629 (W.D.Mich.)

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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ZF MERITOR LLC and MERITOR	)	
TRANSMISSION CORPORATION,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civ. No. 06-623-SLR
	)	
EATON CORPORATION,	)	
	)	
Defendant.	)	

**ORDER**

At Wilmington this 13th day of June, 2007, having reviewed the papers filed in connection with defendant's motions to dismiss or, in the alternative, to transfer;

IT IS ORDERED that said motions (D.I. 7, 9) are denied, for the reasons that follow:

1. **Motion to dismiss.** In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all material allegations of the complaint and it must construe the complaint in favor of the plaintiff. See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." Id. Claims may be dismissed pursuant to a Rule 12(b)(6) motion only if the plaintiff cannot demonstrate any set of facts that would entitle him to relief. See Conley v. Gibson, 355



U.S. 41, 45-46 (1957). The moving party has the burden of persuasion. See Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991).

2. Defendant posits that dismissal of this case, before the completion of discovery, is warranted because the complaint describes "competitive" conduct, not "anticompetitive" conduct; hence, there cannot be antitrust injury. In support of its motion, defendant describes its version of the facts related to the health of the trucking industry and its reaction to such over the last decade. While the court recognizes that antitrust litigation is a burden, the court cannot dismiss a case based on the defendant's characterization of the relevant facts at this stage of the proceedings. The court, instead, will expect the parties to be prepared at the scheduling conference to talk about staged discovery in order to target the evidence necessary to resolve this case fairly and efficiently.

3. **Motion to transfer.** Under 28 U.S.C. § 1404(a), a district court may transfer any civil action to any other district where the action might have been brought for the convenience of parties and witnesses and in the interests of justice. Congress intended through § 1404 to place discretion in the district court to adjudicate motions to transfer according to an individualized, case-by-case consideration of convenience and the interests of justice. Stewart Org., Inc. v. Ricoh Corp., 487 U.S. 22, 29 (1988); Affymetrix, Inc. v. Synteni, Inc., 28 F. Supp.2d 192, 208 (D. Del. 1998). The burden of establishing the need to transfer rests with the movant "to establish that the balance of convenience of the parties and witnesses strongly favors the defendants." Bergman v. Brainin, 512 F. Supp. 972, 973 (D. Del. 1981) (citing Shutte v. Armco Steel Corp., 431 F.2d 22, 25 (3d Cir. 1970)). "Unless the balance is strongly in favor of a transfer, the



plaintiff's choice of forum should prevail". ADE Corp. v. KLA-Tencor Corp., 138 F. Supp.2d 565, 567 (D. Del. 2001); Shutte, 431 F.2d at 25.

4. Plaintiffs are incorporated in Delaware. Defendant is a billion-dollar company with nationwide operations that has litigated in Delaware on multiple occasions. Discovery will take place nationwide, regardless of where trial is conducted. In this day and age, most witnesses are presented at trial via electronically recorded depositions rather than presented live. At this stage of the proceedings, therefore, defendant has presented to the court neither a viable obstacle to conducting trial in Delaware nor a persuasive reason of convenience to conducting trial elsewhere.

  
United States District Judge